

US3112119 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:10:35

All time stamps listed in this document are displayed in GMT

US3112119

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:00:19

Generated On: 09 Jun 2021 15:10:35

Participant ID

US3112119

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

US3112119

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3112119

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:45:12

Generated On: 09 Jun 2021 15:10:35

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
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	False
Black	False
Asian	True
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

US3112119

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Date of Informed Consent (*dd MMM yyyy*) 5 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3112119

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3112119

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Were any significant conditions reported?

Yes ☒

No ☐

US3112119

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3112119

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3112119

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:05 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 15:05
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	184.2 lb
BMI (<i>xxx.x</i>)	32.69779 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112119

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

US3112119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

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

(b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3112119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:45:13

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101432

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 ☒

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Height	ND - Not Done
Weight	ND - Not Done

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 15:05
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	090 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	17:09 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 17:09
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	088 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

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.

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

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) 5 AUG 2020

What was the treatment time? (00:00-23:59) 16:38 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 16:38

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

US3112119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 AUG 2020
Collection time (00:00-23:59)	15:45 (24 HR)
Collection date and time (derived)	5 AUG 2020 15:45

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:38	5 AUG 2020 15:38
Nasopharyngeal Swab 2	No		

US3112119

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 17:11

PC Open Date & Time

05 AUG 2020 16:58

PC Close Date & Time

05 AUG 2020 19:28

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

97.7 °F

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

Yes ☐
No ☒

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

PC Time Stamp	05 AUG 2020 23:29
PC Open Date & Time	05 AUG 2020 20:23
PC Close Date & Time	06 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 15:22

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:07

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:47

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

09 AUG 2020 13:11

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 23:55

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 17:12

PC Open Date & Time

05 AUG 2020 16:58

PC Close Date & Time

05 AUG 2020 19:28

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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 AUG 2020 23:30

PC Open Date & Time

05 AUG 2020 20:23

PC Close Date & Time

06 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 15:22

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 12:08

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 18:47

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 13:11

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 23:55

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 17:13
PC Open Date & Time	05 AUG 2020 16:58
PC Close Date & Time	05 AUG 2020 19:28

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 23:30
PC Open Date & Time	05 AUG 2020 20:23
PC Close Date & Time	06 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 15:22
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:48
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2509

EAB) (1725)

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2509

EAB) (1725)

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 23:55
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

53 of 2509

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

Yes ☐

PC Time stamp

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

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)	03 SEP 2020
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 16:35
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

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)	03 SEP 2020
Time of assessment (00:00-23:59)	17:40 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 17:40
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 17:09 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 17:09

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

What was the frequency of the study treatment dosing? ONCE

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

US3112119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	16:51 (24 HR)
Collection date and time (derived)	3 SEP 2020 16:51

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:46	3 SEP 2020 16:46
Nasopharyngeal Swab 2	No		

US3112119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 17:38

PC Open Date & Time

03 SEP 2020 17:29

PC Close Date & Time

03 SEP 2020 19:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp	03 SEP 2020 22:42
PC Open Date & Time	03 SEP 2020 20:54
PC Close Date & Time	04 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 14:51

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

08 SEP 2020 19:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

09 SEP 2020 13:24

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

03 SEP 2020 17:38

PC Open Date & Time

03 SEP 2020 17:29

PC Close Date & Time

03 SEP 2020 19:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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

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

Yes ☐

No ☒

Please record - **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

03 SEP 2020 22:43

PC Open Date & Time

03 SEP 2020 20:54

PC Close Date & Time

04 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 22:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 14:51

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 13:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 17:39
PC Open Date & Time	03 SEP 2020 17:29
PC Close Date & Time	03 SEP 2020 19:59

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 22:43
---------------	-------------------

PC Open Date & Time	03 SEP 2020 20:54
---------------------	-------------------

PC Close Date & Time	04 SEP 2020 11:59
----------------------	-------------------

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:23
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

91 of 2509

EAB) (1725)

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:43
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:42
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 14:51
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

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 ☒

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 13:25
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3112119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments FIRST ATTEMPT TO CONTACT
SUBJECT WAS MADE ON
9/11/2020. SUBJECT RETURNED
CALL ON 9/14/2020

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 OCT 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 15:20
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

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.

US3112119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	15:50 (24 HR)
Collection date and time (derived)	5 OCT 2020 15:50

US3112119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:25

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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	05 OCT 2020 10:53:33
Patient Cloud Open Date & Time	05 OCT 2020 00:01
Patient Cloud Close Date & Time	09 OCT 2020 23:59

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 07:17:17
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 04:19:08

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 07:21:00

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	09 NOV 2020 17:08:42
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 22:12:27

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 00:02:08

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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	04 DEC 2020 17:20:38
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 09:21:54

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 16:25:23

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 22:32:38

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 13:40:47
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 08:04:52

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 JAN 2021 07:37:03
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

22 JAN 2021 16:00:40

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 09:10:37

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 09:51:14

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 06:28:12

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

26 FEB 2021 17:38:45

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 215

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 <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	14 MAR 2021 23:39:01
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 20:08:09

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	02 APR 2021 07:21:28
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

13 APR 2021 13:22:43

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:48:14

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

30 APR 2021 06:25:26

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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°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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2021 23:59
---	-------------------

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

Patient Cloud Open Date & Time	24 SEP 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	28 SEP 2021 23:59
---	-------------------

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

Patient Cloud Open Date & Time	16 SEP 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	20 SEP 2022 23:59
---	-------------------

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

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

Date and time of submission

Patient Cloud Open Date & Time	07 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	11 OCT 2022 23:59
---	-------------------

US3112119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:10:35

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		01 MAR 2021 15:30:40

US3112119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:45:03

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:45:03

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

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

Visit date (dd MMM yyyy)	2 MAR 2021
--------------------------	------------

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

Folder OID	VISIT4
------------	--------

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	15:57 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 15:57
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

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.

US3112119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3112119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112119

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:10:35

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"/>

US3112119

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:10:35

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3112119

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

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

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

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

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

US3112119

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 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>)	7 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

US3112119

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3112119

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

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)	7 JAN 2021
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 15:15
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

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)	7 JAN 2021
Time of assessment (00:00-23:59)	16:21 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 16:21
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 JAN 2021

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

US3112119

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

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) 7 JAN 2021

What was the treatment time? (00:00-23:59) 15:50 (24 HR)

Treatment Date and Time (derived) 7 JAN 2021 15:50

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

US3112119

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

Collection time (00:00-23:59)	15:26 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	7 JAN 2021 15:26
------------------------------------	------------------

US3112119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

Collection time (00:00 - 23:59)	15:21
---------------------------------	-------

Collection Date and Time (derived)	7 JAN 2021 15:21
------------------------------------	------------------

US3112119

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3112119

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

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)	4 FEB 2021
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 15:06
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	4 FEB 2021
Time of assessment (00:00-23:59)	16:01 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 16:01
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3112119

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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

US3112119

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

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) 4 FEB 2021

What was the treatment time? (00:00-23:59) 15:30 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 15:30

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

What was the frequency of the study treatment dosing? ONCE

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

US3112119

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3112119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:44

Generated On: 09 Jun 2021 15:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112119

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

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

Visit date (dd MMM yyyy)	2 MAR 2021
--------------------------	------------

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

Folder OID	OLD57
------------	-------

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:57 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 15:57
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112119

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

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.

US3112119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 2 MAR 2021

Collection time (00:00-23:59) 16:06 (24 HR)

Collection date and time (derived) 2 MAR 2021 16:06

US3112119

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:20:29

Generated On: 09 Jun 2021 15:10:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:02:15

Generated On: 09 Jun 2021 15:10:35

AEID	USA-US062-2021-MRNA-1273-P30 1000015
Adverse event	CHOLECYSTITIS SECONDARY TO CHOLELITHIASIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 APR 2021
Hospital Discharge Date (dd MMM yyyy)	02 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	340 of 2509

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:02:15

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:02:15

Generated On: 09 Jun 2021 15:10:35

PT. WITH HISTORY OF
CHOLELITHIASIS. DIAGNOSIS
FOLLOWING STUDY
ENROLLMENT. PT. NOW
ADMITTED TO HOSPITAL WITH
NEW CHOLECYSTITIS.
SURGERY BEING PURSUED FOR
EVOLUTION OF DISEASE. WILL
REQUEST MEDICAL RECORDS
AND FOLLOW UP.

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

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:02:15

Generated On: 09 Jun 2021 15:10:35

AEID	
Adverse event	CHOLELITHIASIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2509

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:02:15

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:00:43

Generated On: 09 Jun 2021 15:10:35

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

Yes ☒

No ☐

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

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

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)

346 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	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 1999
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication TRULICITY

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 1.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

348 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

350 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication DIOVAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 160

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)

352 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	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 1999
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication HEALTH SUPPLEMENT

Dose per administration 5000

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

THREE TIMES PER WEEK

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

PRODUCTION RELEASE (v12.003

354 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication HEALTH 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

3 TIMES PER WEEK

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

PRODUCTION RELEASE (v12.003

356 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication HEALTH SUPPLEMENT

Dose per administration 5000

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

TWICE PER WEEK

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

PRODUCTION RELEASE (v12.003

358 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU VACCINE

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

360 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE/BODY ACHE AND
HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	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)	05 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication POST LAPAROSCOPIC
CHOLESCYSTECTOMY PAIN
RELIEF

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)

364 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN SECONDARY
TO CHOLELITHIASIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	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)		31 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication MYLANTA (MAGNESIUM
HYDROXIDE, ALUMINIUM
HYDROXIDE, SIMETHICONE)

Prophylaxis Yes ☐
No ☒

Indication ABDOMINA PAIN SECONDARY
TO CHOLELITHIASIS

Dose per administration 1

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

If dose unit is Other, specify TABLE SPOON

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication POST LAPAROSCOPIC
CHOLECYSTECTOMY PAIN
RELIEF

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication POST LAPAROSCOPIC
CHOLECYSTECTOMY

Dose per administration 1

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

If dose unit is Other, specify TABLE SPOON

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)

372 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	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)	02 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication SENNA

Prophylaxis Yes ☐
No ☒

Indication POST LAPAROSCOPIC
CHOLECYSTECTOMY

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	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)	02 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication OZEMPIC

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 0.25 OR 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)

376 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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

380 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 0.2 OR 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

Q4H PRN

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

PRODUCTION RELEASE (v12.003

382 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRADERMAL
Start date (dd MMM yyyy)		01 APR 2021
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2021
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

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

Q4H PRN

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

PRODUCTION RELEASE (v12.003

386 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication NARCAN

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 0.1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q2MIN PRN

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	02 APR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

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)

390 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q8H

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

PRODUCTION RELEASE (v12.003

392 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

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)

394 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication METAMUCIL

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 1

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

If dose unit is Other, specify PACKET

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)

396 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication LACTULOSE

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

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

398 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication BISACODYL

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

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)

400 of 2509

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q6H PRN

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

PRODUCTION RELEASE (v12.003

402 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 02 APR 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

Name of Medication MILK OF MAGNESIA

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

404 of 2509

EAB) (1725)

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 22:48:43

Generated On: 09 Jun 2021 15:10:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3112119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 23:34:51

Generated On: 09 Jun 2021 15:10:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 APR 2021	LAPAROSCOPIC CHOLECYSTECTOMY	Adverse Event	

US3112119

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:10:35

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

US3112119

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:10:35

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 ☐

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

SAEID	USA-US062-2021-MRNA-1273-P301000015
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

SAEID	USA-US062-2021-MRNA-1273-P301000015
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/APR/2021 11:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

SAEID	USA-US062-2021-MRNA-1273-P301000015
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	07/APR/2021 16:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

SAEID	USA-US062-2021-MRNA-1273-P301000015
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 16:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

SAEID	USA-US062-2021-MRNA-1273-P301000015
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	14/APR/2021 09:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

SAEID	USA-US062-2021-MRNA-1273-P301000015
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 10:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Apr 2021 21:02:16

Generated On: 09 Jun 2021 15:10:35

SAEID	USA-US062-2021-MRNA-1273-P301000015
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/APR/2021 10:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3112119 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112119

Form: Participant Creation

Generated On: 09 Jun 2021 15:10:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'US3112119'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 22:49:13

US3112119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 23:48:58

US3112119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 22:49:14

US3112119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	05 Aug 2020 23:48:58

US3112119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'SCRN'	System	05 Aug 2020 23:48:58

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 22:49:15

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '49'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'YEARS'	System	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered '49'	System	05 Aug 2020 23:49:09

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Male (M)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'I'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:35

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:28:54

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '5 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 23:49:09

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'Aug 2020'	System	05 Aug 2020 23:49:09

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered '2020'	System	05 Aug 2020 23:49:09

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Amendment 1 (1)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 23:49:09

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 23:49:09

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	(b) (4) Matthew Musikanth	05 Aug 2020 23:49:09
	(b) (4)	

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	(b) (4) Matthew Musikanth	05 Aug 2020 23:49:09
	(b) (4)	

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 23:49:09

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 22:49:14

US3112119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'I'	System	05 Aug 2020 23:49:13

US3112119

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 23:49:13

US3112119

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:10:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 02:34:08
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'Med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:01
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:55:56
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:29:03

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:30:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:30:38
Data point term sent to Coder	System	05 Sep 2020 19:30:01
User entered 'Hypertension'	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'UN UNK 1999'	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'Jan 1999'	System	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered '1999'	System	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered empty.	System	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered empty.	System	05 Sep 2020 19:29:25

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:31:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:31:38
Data point term sent to Coder	System	05 Sep 2020 19:31:04
User entered 'Type II Diabetes'	Karen Mylerberg (b) (4)	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'UN UNK 1999'	Karen Mylerberg (b) (4)	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'Jan 1999'	System	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered '1999'	System	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered empty.	System	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered empty.	System	05 Sep 2020 19:30:13

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '15:05'	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered '5 Aug 2020 15:05'	System	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '63' in	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53
DataPoint set to visible.	System	05 Aug 2020 23:49:13

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '184.2' lb	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53
DataPoint set to visible.	System	05 Aug 2020 23:49:13

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
Amendment Manager: User entered '32.69779'	System	16 Sep 2020 23:44:50
User entered '32.7'	System	10 Aug 2020 14:30:53
DataPoint set to visible.	System	05 Aug 2020 23:49:13

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'kg/m2'	System	10 Aug 2020 14:30:53
DataPoint set to visible.	System	05 Aug 2020 23:49:13

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 03:44:31
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Updated ' (Site from DM).	Karen Mylerberg (b) (4)	05 Sep 2020 04:08:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:08:47
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 19:19:21
User entered '98.7' F	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	05 Sep 2020 04:08:47
User entered 'Oral (Oral)'	(b) (4)	
	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53
	(b) (4)	

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:08:47
User entered '78'	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'bpm'	System	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:08:47
User entered '16'	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'breaths/min'	System	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:08:47
User entered '138'	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'mmHg'	System	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:08:47
User entered '090'	Karen Mylerberg (b) (4)	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User entered 'mmHg'	System	10 Aug 2020 14:30:53

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56

US3112119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56

US3112119

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:31:22

US3112119

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
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)	07 Sep 2020 08:48:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 00:19:08
User entered '5 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	10 Aug 2020 14:31:22

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered (b) (6)	(b) (4) Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31
(b) (6)	(b) (4)	

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

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)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered 'I'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:56
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:13
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:31

US3112119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:51

US3112119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:51

US3112119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:32:51

US3112119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'VISIT1'	System	10 Aug 2020 14:32:51

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 22:49:18

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:24:26
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:24:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 22:49:18
User entered '101432' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 22:49:18

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 22:49:18

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:26:31
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:14
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:14
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:21:39
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:39
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:29
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:29
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:34:26

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:26:31
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:14
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:14
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:21:39
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:39
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:29
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:29
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:34:26

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:26:31
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:14
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:14
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:21:39
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:39
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:29
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:29
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:34:26

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 10:30:41
Query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. ' answered with 'Endpoint DCF documentation has been sent, site unable to change stratification post dose. ' (Site from DM).	Matthew Musikanth (b) (4)	10 Nov 2020 18:10:10
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:58:28
Query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	10 Nov 2020 16:58:21
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:26:31
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. (Site from System).	System	23 Sep 2020 18:26:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:14
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. (Site from System).	System	23 Sep 2020 18:26:14
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:14

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Comment added 'Please also note that an IRT data change form has been submitted to change the cohort that the patient is assigned to.'	Nicolle Mendez (b) (4)	23 Sep 2020 18:25:29
Comment added 'Unable to answer query via normal means. This data is confirmed to be entered correctly, the patient is diabetic'.	Nicolle Mendez (b) (4)	23 Sep 2020 18:24:14
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:22:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:22:20
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:22:15
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:22:15
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:22:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:22:08
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:22:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:22:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:22:01
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:22:01
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:22:01
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:39

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:21:39
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:21:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:39
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:29
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:21:29
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:29
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:21:04
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:21:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:04
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:20:59
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Sep 2020 18:20:59
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:20:59
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	10 Aug 2020 14:34:26

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	10 Aug 2020 14:34:26

US3112119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:26:31
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:26:14
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:26:14
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:21:39
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:39
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:21:29
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	23 Sep 2020 18:21:29
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:34:26

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '15:05'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '5 Aug 2020 15:05'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '98.7' F	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '078'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'bpm'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '16'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'breaths/min'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '138'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '090'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4)	18 Aug 2020 16:23:11
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 14:36:40
User entered '17:09'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '5 Aug 2020 17:09'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:18:53
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 19:17:35
User entered '98.2' F	Karen Mylerberg (b) (4) (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '088'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'bpm'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '18'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'breaths/min'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '124'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '082'	Karen Mylerberg (b) (4)	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Aug 2020 14:36:40

US3112119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:10

US3112119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:10

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	05 Aug 2020 23:49:35
	(b) (4)	

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	(b) (4) Matthew Musikanth	05 Aug 2020 23:49:35
	(b) (4)	

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Matthew Musikanth (b) (4)	05 Aug 2020 23:49:35

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 23:49:35

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Aug 2020'	(b) (4) Matthew Musikanth	05 Aug 2020 23:49:35
	(b) (4)	

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '16:38' reason for change: Data Entry Error	(b) (4)	06 Aug 2020 00:00:59
User entered '16:48'	Matthew Musikanth (b) (4)	05 Aug 2020 23:49:35

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '5 Aug 2020 16:38'	System	06 Aug 2020 00:00:59
User entered '5 Aug 2020 16:48'	System	05 Aug 2020 23:49:35

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	05 Aug 2020 23:49:35

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'ONCE'	System	05 Aug 2020 23:49:35

US3112119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 23:49:35

US3112119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:39

US3112119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:39

US3112119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '15:45'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:39

US3112119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '5 Aug 2020 15:45'	System	10 Aug 2020 14:37:39

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '15:38'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '5 Aug 2020 15:38'	System	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered empty.	System	10 Aug 2020 14:37:56

US3112119

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:38:03

US3112119

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '1'	System	10 Aug 2020 14:38:03

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:11:34', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50568b42-2fd0-405e-a11f-0129f111fda8'	System	06 Aug 2020 00:12:01
User entered 'Yes (Y)'	System	06 Aug 2020 00:12:01

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:11:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50568b42-2fd0-405e-a11f-0129f111fda8'	System	06 Aug 2020 00:12:01
User entered '98.2'	System	06 Aug 2020 00:12:01

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:11:50', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50568b42-2fd0-405e-a11f-0129f111fda8'	System	06 Aug 2020 00:12:01
User entered 'No (N)'	System	06 Aug 2020 00:12:01

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:11:57', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50568b42-2fd0-405e-a11f-0129f111fda8'	System	06 Aug 2020 00:12:01
User entered '05 Aug 2020 17:11'	System	06 Aug 2020 00:12:01

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 16:58'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 17:08'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 19:28'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 19:38'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:29:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd79e9ba5-6140-4d68-8acc-ecca40245ba4'	System	06 Aug 2020 06:29:58
User entered 'Yes (Y)'	System	06 Aug 2020 06:29:58

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:29:44', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd79e9ba5-6140-4d68-8acc-ecca40245ba4' User entered '97.7'	System	06 Aug 2020 06:29:58
	System	06 Aug 2020 06:29:58

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:29:50', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd79e9ba5-6140-4d68-8acc-ecca40245ba4'	System	06 Aug 2020 06:29:58
User entered 'No (N)'	System	06 Aug 2020 06:29:58

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:29:53', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd79e9ba5-6140-4d68-8acc-ecca40245ba4'	System	06 Aug 2020 06:29:58
User entered '05 Aug 2020 23:29'	System	06 Aug 2020 06:29:58

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 20:23'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 20:33'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 2'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:21:43', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '9bf81f03-6b2e-453f-a007-eb8c9ae682b2'	System	06 Aug 2020 22:22:06
User entered 'Yes (Y)'	System	06 Aug 2020 22:22:06

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:21:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '9bf81f03-6b2e-453f-a007-eb8c9ae682b2'	System	06 Aug 2020 22:22:06
User entered '97.7'	System	06 Aug 2020 22:22:06

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:21:57', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '9bf81f03-6b2e-453f-a007-eb8c9ae682b2'	System	06 Aug 2020 22:22:06
User entered 'No (N)'	System	06 Aug 2020 22:22:06

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:02', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '9bf81f03-6b2e-453f-a007-eb8c9ae682b2'	System	06 Aug 2020 22:22:06
User entered '06 Aug 2020 15:22'	System	06 Aug 2020 22:22:06

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 3'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:07:15', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a2ced087-9023-483b-9f21-e4a3e172fdff'	System	07 Aug 2020 19:07:38
User entered 'Yes (Y)'	System	07 Aug 2020 19:07:38

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:07:25', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a2ced087-9023-483b-9f21-e4a3e172fdff'	System	07 Aug 2020 19:07:38
User entered '97.7'	System	07 Aug 2020 19:07:38

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:07:32', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a2ced087-9023-483b-9f21-e4a3e172fdff'	System	07 Aug 2020 19:07:38
User entered 'No (N)'	System	07 Aug 2020 19:07:38

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:07:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a2ced087-9023-483b-9f21-e4a3e172fdff'	System	07 Aug 2020 19:07:38
User entered '07 Aug 2020 12:07'	System	07 Aug 2020 19:07:38

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 4'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:30', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '68be5397-cb2f-429c-961d-ff292dab10f3'	System	09 Aug 2020 01:47:49
User entered 'Yes (Y)'	System	09 Aug 2020 01:47:49

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '68be5397-cb2f-429c-961d-ff292dab10f3'	System	09 Aug 2020 01:47:49
User entered '98.2'	System	09 Aug 2020 01:47:49

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '68be5397-cb2f-429c-961d-ff292dab10f3'	System	09 Aug 2020 01:47:49
User entered 'No (N)'	System	09 Aug 2020 01:47:49

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '68be5397-cb2f-429c-961d-ff292dab10f3'	System	09 Aug 2020 01:47:49
User entered '08 Aug 2020 18:47'	System	09 Aug 2020 01:47:49

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 5'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:17', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c9c4c3fe-b56c-47e6-b180-42227e1853d2'	System	09 Aug 2020 20:11:34
User entered 'Yes (Y)'	System	09 Aug 2020 20:11:34

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:25', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c9c4c3fe-b56c-47e6-b180-42227e1853d2'	System	09 Aug 2020 20:11:34
User entered '97.6'	System	09 Aug 2020 20:11:34

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:28', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c9c4c3fe-b56c-47e6-b180-42227e1853d2'	System	09 Aug 2020 20:11:34
User entered 'No (N)'	System	09 Aug 2020 20:11:34

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:30', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c9c4c3fe-b56c-47e6-b180-42227e1853d2'	System	09 Aug 2020 20:11:34
User entered '09 Aug 2020 13:11'	System	09 Aug 2020 20:11:34

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 6'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:54:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0dd70567-d50c-4846-afb7-c4184621ec3f'	System	11 Aug 2020 06:55:07
User entered 'Yes (Y)'	System	11 Aug 2020 06:55:07

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:54:58', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0dd70567-d50c-4846-afb7-c4184621ec3f' User entered '97.8'	System	11 Aug 2020 06:55:07
	System	11 Aug 2020 06:55:07

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0dd70567-d50c-4846-afb7-c4184621ec3f'	System	11 Aug 2020 06:55:07
User entered 'No (N)'	System	11 Aug 2020 06:55:07

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0dd70567-d50c-4846-afb7-c4184621ec3f'	System	11 Aug 2020 06:55:07
User entered '10 Aug 2020 23:55'	System	11 Aug 2020 06:55:07

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 7'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:12:15', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dcebca63-31f2-44a0-b2aa-8c4c66766853'	System	06 Aug 2020 00:12:49
User entered 'None (1)'	System	06 Aug 2020 00:12:49

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:12:18', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dcebca63-31f2-44a0-b2aa-8c4c66766853'	System	06 Aug 2020 00:12:49
User entered 'No (N)'	System	06 Aug 2020 00:12:49

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:12:28', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dcebca63-31f2-44a0-b2aa-8c4c66766853'	System	06 Aug 2020 00:12:49
User entered 'No (N)'	System	06 Aug 2020 00:12:49

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:12:41', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dcebca63-31f2-44a0-b2aa-8c4c66766853'	System	06 Aug 2020 00:12:49
User entered 'None (1)'	System	06 Aug 2020 00:12:49

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:12:45', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dcebca63-31f2-44a0-b2aa-8c4c66766853'	System	06 Aug 2020 00:12:49
User entered '05 Aug 2020 17:12'	System	06 Aug 2020 00:12:49

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 16:58'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 17:08'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 19:28'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 19:38'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:29:59', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '43ce01cd-96a9-4283-9ee0-c10158ebabda'	System	06 Aug 2020 06:30:14
User entered 'None (1)'	System	06 Aug 2020 06:30:14

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:02', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '43ce01cd-96a9-4283-9ee0-c10158ebabda'	System	06 Aug 2020 06:30:14
User entered 'No (N)'	System	06 Aug 2020 06:30:14

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '43ce01cd-96a9-4283-9ee0-c10158ebabda'	System	06 Aug 2020 06:30:14
User entered 'No (N)'	System	06 Aug 2020 06:30:14

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:09', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '43ce01cd-96a9-4283-9ee0-c10158ebabda'	System	06 Aug 2020 06:30:14
User entered 'None (1)'	System	06 Aug 2020 06:30:14

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '43ce01cd-96a9-4283-9ee0-c10158ebabda'	System	06 Aug 2020 06:30:14
User entered '05 Aug 2020 23:30'	System	06 Aug 2020 06:30:14

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 20:23'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 20:33'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 2'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:15', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fb7e695-cd07-4647-a62e-dab83c425fd1'	System	06 Aug 2020 22:22:33
User entered 'None (1)'	System	06 Aug 2020 22:22:33

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:21', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fb7e695-cd07-4647-a62e-dab83c425fd1'	System	06 Aug 2020 22:22:33
User entered 'No (N)'	System	06 Aug 2020 22:22:33

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:24', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fb7e695-cd07-4647-a62e-dab83c425fd1'	System	06 Aug 2020 22:22:33
User entered 'No (N)'	System	06 Aug 2020 22:22:33

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:27', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fb7e695-cd07-4647-a62e-dab83c425fd1'	System	06 Aug 2020 22:22:33
User entered 'None (1)'	System	06 Aug 2020 22:22:33

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:31', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fb7e695-cd07-4647-a62e-dab83c425fd1'	System	06 Aug 2020 22:22:33
User entered '06 Aug 2020 15:22'	System	06 Aug 2020 22:22:33

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 3'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:07:48', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '10ae13a2-07e8-4119-92ee-92c15cd2c1f9'	System	07 Aug 2020 19:08:07
User entered 'None (1)'	System	07 Aug 2020 19:08:07

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:07:53', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '10ae13a2-07e8-4119-92ee-92c15cd2c1f9'	System	07 Aug 2020 19:08:07
User entered 'No (N)'	System	07 Aug 2020 19:08:07

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:07:58', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '10ae13a2-07e8-4119-92ee-92c15cd2c1f9'	System	07 Aug 2020 19:08:07
User entered 'No (N)'	System	07 Aug 2020 19:08:07

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '10ae13a2-07e8-4119-92ee-92c15cd2c1f9'	System	07 Aug 2020 19:08:07
User entered 'None (1)'	System	07 Aug 2020 19:08:07

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '10ae13a2-07e8-4119-92ee-92c15cd2c1f9'	System	07 Aug 2020 19:08:07
User entered '07 Aug 2020 12:08'	System	07 Aug 2020 19:08:07

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 4'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:47', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '14b353de-0957-425c-b999-1ed6bc4dc071'	System	09 Aug 2020 01:48:00
User entered 'None (1)'	System	09 Aug 2020 01:48:00

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:50', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '14b353de-0957-425c-b999-1ed6bc4dc071'	System	09 Aug 2020 01:48:00
User entered 'No (N)'	System	09 Aug 2020 01:48:00

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '14b353de-0957-425c-b999-1ed6bc4dc071'	System	09 Aug 2020 01:48:00
User entered 'No (N)'	System	09 Aug 2020 01:48:00

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:53', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '14b353de-0957-425c-b999-1ed6bc4dc071'	System	09 Aug 2020 01:48:00
User entered 'None (1)'	System	09 Aug 2020 01:48:00

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:55', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '14b353de-0957-425c-b999-1ed6bc4dc071'	System	09 Aug 2020 01:48:00
User entered '08 Aug 2020 18:47'	System	09 Aug 2020 01:48:00

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 5'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:34', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '24064291-0362-49f3-b2b5-d1c1b9fd8993'	System	09 Aug 2020 20:11:50
User entered 'None (1)'	System	09 Aug 2020 20:11:50

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '24064291-0362-49f3-b2b5-d1c1b9fd8993'	System	09 Aug 2020 20:11:50
User entered 'No (N)'	System	09 Aug 2020 20:11:50

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '24064291-0362-49f3-b2b5-d1c1b9fd8993'	System	09 Aug 2020 20:11:50
User entered 'No (N)'	System	09 Aug 2020 20:11:50

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:41', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '24064291-0362-49f3-b2b5-d1c1b9fd8993'	System	09 Aug 2020 20:11:50
User entered 'None (1)'	System	09 Aug 2020 20:11:50

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:43', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '24064291-0362-49f3-b2b5-d1c1b9fd8993'	System	09 Aug 2020 20:11:50
User entered '09 Aug 2020 13:11'	System	09 Aug 2020 20:11:50

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 6'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:09', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'fa11df13-9486-4fdf-a54f-14872a065675'	System	11 Aug 2020 06:55:23
User entered 'None (1)'	System	11 Aug 2020 06:55:23

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:13', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'fa11df13-9486-4fdf-a54f-14872a065675'	System	11 Aug 2020 06:55:23
User entered 'No (N)'	System	11 Aug 2020 06:55:23

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:15', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'fa11df13-9486-4fdf-a54f-14872a065675'	System	11 Aug 2020 06:55:23
User entered 'No (N)'	System	11 Aug 2020 06:55:23

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:17', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'fa11df13-9486-4fdf-a54f-14872a065675'	System	11 Aug 2020 06:55:23
User entered 'None (1)'	System	11 Aug 2020 06:55:23

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:19', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'fa11df13-9486-4fdf-a54f-14872a065675'	System	11 Aug 2020 06:55:23
User entered '10 Aug 2020 23:55'	System	11 Aug 2020 06:55:23

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 7'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:12:54', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered 'None (0)'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:13:02', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered 'None (0)'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:13:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered 'None (0)'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:13:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered 'None (0)'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:13:13', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered 'None (0)'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:13:15', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered 'None (0)'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:13:22', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered 'No (N)'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T17:13:27', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f34c758a-97da-4a8f-b567-8e24002c55af'	System	06 Aug 2020 00:13:30
User entered '05 Aug 2020 17:13'	System	06 Aug 2020 00:13:30

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 16:58'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 17:08'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 19:28'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 19:38'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:19', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered 'None (0)'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:23', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered 'None (0)'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:26', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered 'None (0)'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:28', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered 'None (0)'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:30', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered 'None (0)'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:33', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered 'None (0)'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:35', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered 'No (N)'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-05T23:30:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50c6ce34-583c-4ee7-982e-5f37fa6a9712'	System	06 Aug 2020 06:30:42
User entered '05 Aug 2020 23:30'	System	06 Aug 2020 06:30:42

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Aug 2020 20:23'	System	06 Aug 2020 00:00:59
User entered '05 Aug 2020 20:33'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 2'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:35', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered 'None (0)'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered 'None (0)'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:40', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered 'None (0)'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered 'None (0)'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:44', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered 'None (0)'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:46', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered 'None (0)'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:48', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered 'No (N)'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-06T15:22:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'b3f19763-ba9a-41c5-9e18-2d3f415451b7'	System	06 Aug 2020 22:22:54
User entered '06 Aug 2020 15:22'	System	06 Aug 2020 22:22:54

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 3'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:09', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered 'None (0)'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered 'None (0)'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:12', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered 'None (0)'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:13', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered 'None (0)'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered 'None (0)'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:16', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered 'None (0)'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:17', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered 'No (N)'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-07T12:08:20', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bf062b5a-2072-4af0-af84-a658ac8f8e84'	System	07 Aug 2020 19:08:24
User entered '07 Aug 2020 12:08'	System	07 Aug 2020 19:08:24

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 4'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:47:59', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered 'None (0)'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:48:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered 'None (0)'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:48:02', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered 'None (0)'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:48:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered 'None (0)'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:48:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered 'None (0)'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:48:07', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered 'None (0)'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:48:08', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered 'No (N)'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-08T18:48:10', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55156bf0-a9d6-402b-a39a-a5fae7e5c3a5'	System	09 Aug 2020 01:48:16
User entered '08 Aug 2020 18:48'	System	09 Aug 2020 01:48:16

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 5'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:49', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered 'None (0)'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered 'None (0)'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:53', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered 'None (0)'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:56', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered 'None (0)'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:11:58', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered 'None (0)'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:12:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered 'None (0)'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:12:02', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered 'No (N)'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-09T13:12:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '50648c56-1524-4706-9596-471d07a16fa9'	System	09 Aug 2020 20:12:11
User entered '09 Aug 2020 13:12'	System	09 Aug 2020 20:12:11

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 6'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:24', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered 'None (0)'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:26', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered 'None (0)'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:28', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered 'None (0)'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:30', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered 'None (0)'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:32', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered 'None (0)'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:34', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered 'None (0)'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:37', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered 'No (N)'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-08-10T23:55:39', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '732d2883-7fac-4ae2-a70d-5dcb010b77e7'	System	11 Aug 2020 06:55:41
User entered '10 Aug 2020 23:55'	System	11 Aug 2020 06:55:41

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 7'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 23:49:35

US3112119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 00:58:42

US3112119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 00:58:42

US3112119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 00:58:42

US3112119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 00:58:42

US3112119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 00:58:47

US3112119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	13 Aug 2020 00:58:47

US3112119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:31:24

US3112119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:31:24

US3112119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:31:24

US3112119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:31:24

US3112119

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:31:36

US3112119

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	19 Aug 2020 22:31:36

US3112119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:59:11

US3112119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:59:11

US3112119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:59:11

US3112119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:59:11

US3112119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:59:20

US3112119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	26 Aug 2020 17:59:20

US3112119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:08

US3112119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:08

US3112119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:08

US3112119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'VISIT2'	System	04 Sep 2020 00:19:08

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '03 Sep 2020'	(b) (4) Matthew Musikanth	10 Sep 2020 00:54:13
	(b) (4)	

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '16:35'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '03 Sep 2020 16:35'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '98.7' F	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	(b) (4) Matthew Musikanth	10 Sep 2020 00:54:13
	(b) (4)	

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '95'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'bpm'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '16'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'breaths/min'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '109'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '79'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '03 Sep 2020'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '17:40'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '03 Sep 2020 17:40'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '98.3' F	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	(b) (4) Matthew Musikanth	10 Sep 2020 00:54:13
	(b) (4)	

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '98'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'bpm'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '18'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'breaths/min'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '128'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '88'	Matthew Musikanth (b) (4)	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	10 Sep 2020 00:54:13

US3112119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	19 Oct 2020 14:47:19
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:31:53

US3112119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '3 Sep 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	19 Oct 2020 14:47:19
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 19:31:53

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '17:09'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '3 Sep 2020 17:09'	System	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'ONCE'	System	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 00:19:24

US3112119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:11

US3112119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '3 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:11

US3112119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '16:51'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:11

US3112119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '3 Sep 2020 16:51'	System	05 Sep 2020 19:32:11

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '3 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '16:46'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '3 Sep 2020 16:46'	System	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered empty.	System	05 Sep 2020 19:32:32

US3112119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 00:19:29

US3112119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	04 Sep 2020 00:19:29

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:37:46', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '145debab-e8c1-4fd3-b7b2-d61c0c28154d'	System	04 Sep 2020 00:38:23
User entered 'Yes (Y)'	System	04 Sep 2020 00:38:23

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:37:52', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '145debab-e8c1-4fd3-b7b2-d61c0c28154d'	System	04 Sep 2020 00:38:23
User entered '98.3'	System	04 Sep 2020 00:38:23

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:37:58', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '145debab-e8c1-4fd3-b7b2-d61c0c28154d'	System	04 Sep 2020 00:38:23
User entered 'No (N)'	System	04 Sep 2020 00:38:23

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:08', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '145debab-e8c1-4fd3-b7b2-d61c0c28154d'	System	04 Sep 2020 00:38:23
User entered '03 Sep 2020 17:38'	System	04 Sep 2020 00:38:23

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 17:29'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 19:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:42:34', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0ea04b99-0ca3-488c-9969-2d43251bc7f8'	System	04 Sep 2020 05:42:59
User entered 'Yes (Y)'	System	04 Sep 2020 05:42:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:42:41', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0ea04b99-0ca3-488c-9969-2d43251bc7f8'	System	04 Sep 2020 05:42:59
User entered '97.8'	System	04 Sep 2020 05:42:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:42:47', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0ea04b99-0ca3-488c-9969-2d43251bc7f8'	System	04 Sep 2020 05:42:59
User entered 'No (N)'	System	04 Sep 2020 05:42:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:42:55', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0ea04b99-0ca3-488c-9969-2d43251bc7f8'	System	04 Sep 2020 05:42:59
User entered '03 Sep 2020 22:42'	System	04 Sep 2020 05:42:59

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 20:54'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 2'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:18', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7cc176cf-4ff8-4bcb-9ff1-f705845892a2'	System	04 Sep 2020 19:21:38
User entered 'Yes (Y)'	System	04 Sep 2020 19:21:38

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:29', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7cc176cf-4ff8-4bcb-9ff1-f705845892a2'	System	04 Sep 2020 19:21:38
User entered '98.2'	System	04 Sep 2020 19:21:38

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:33', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7cc176cf-4ff8-4bcb-9ff1-f705845892a2'	System	04 Sep 2020 19:21:38
User entered 'No (N)'	System	04 Sep 2020 19:21:38

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7cc176cf-4ff8-4bcb-9ff1-f705845892a2'	System	04 Sep 2020 19:21:38
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 19:21:38

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 3'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:29', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bcf8945c-4f8f-4ac7-98b6-5822edc7b70b'	System	06 Sep 2020 03:42:44
User entered 'Yes (Y)'	System	06 Sep 2020 03:42:44

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bcf8945c-4f8f-4ac7-98b6-5822edc7b70b'	System	06 Sep 2020 03:42:44
User entered '98.1'	System	06 Sep 2020 03:42:44

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:39', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bcf8945c-4f8f-4ac7-98b6-5822edc7b70b'	System	06 Sep 2020 03:42:44
User entered 'No (N)'	System	06 Sep 2020 03:42:44

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'bcf8945c-4f8f-4ac7-98b6-5822edc7b70b'	System	06 Sep 2020 03:42:44
User entered '05 Sep 2020 20:42'	System	06 Sep 2020 03:42:44

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 4'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a35d2ef6-d27d-451c-9dbc-c4c0f557efe8'	System	07 Sep 2020 05:41:43
User entered 'Yes (Y)'	System	07 Sep 2020 05:41:43

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:23', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a35d2ef6-d27d-451c-9dbc-c4c0f557efe8' User entered '98.2'	System	07 Sep 2020 05:41:43
	System	07 Sep 2020 05:41:43

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:26', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a35d2ef6-d27d-451c-9dbc-c4c0f557efe8'	System	07 Sep 2020 05:41:43
User entered 'No (N)'	System	07 Sep 2020 05:41:43

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a35d2ef6-d27d-451c-9dbc-c4c0f557efe8'	System	07 Sep 2020 05:41:43
User entered '06 Sep 2020 22:41'	System	07 Sep 2020 05:41:43

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 5'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '5293e80d-b794-46ee-8238-2b5abf3307d7'	System	07 Sep 2020 21:51:16
User entered 'Yes (Y)'	System	07 Sep 2020 21:51:16

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:10', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '5293e80d-b794-46ee-8238-2b5abf3307d7'	System	07 Sep 2020 21:51:16
User entered '98.0'	System	07 Sep 2020 21:51:16

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:12', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '5293e80d-b794-46ee-8238-2b5abf3307d7'	System	07 Sep 2020 21:51:16
User entered 'No (N)'	System	07 Sep 2020 21:51:16

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '5293e80d-b794-46ee-8238-2b5abf3307d7'	System	07 Sep 2020 21:51:16
User entered '07 Sep 2020 14:51'	System	07 Sep 2020 21:51:16

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 6'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:09', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7e91a51f-0a82-4757-a859-399f2f6b98df'	System	09 Sep 2020 02:26:27
User entered 'Yes (Y)'	System	09 Sep 2020 02:26:27

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:19', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7e91a51f-0a82-4757-a859-399f2f6b98df' User entered '97.9'	System	09 Sep 2020 02:26:27
	System	09 Sep 2020 02:26:27

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:22', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7e91a51f-0a82-4757-a859-399f2f6b98df'	System	09 Sep 2020 02:26:27
User entered 'No (N)'	System	09 Sep 2020 02:26:27

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:25', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '7e91a51f-0a82-4757-a859-399f2f6b98df'	System	09 Sep 2020 02:26:27
User entered '08 Sep 2020 19:26'	System	09 Sep 2020 02:26:27

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 7'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:35', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '621b3123-3578-4ac8-b629-1d97e076b681'	System	09 Sep 2020 20:24:50
User entered 'Yes (Y)'	System	09 Sep 2020 20:24:50

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:41', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '621b3123-3578-4ac8-b629-1d97e076b681' User entered '97.4'	System	09 Sep 2020 20:24:50
	System	09 Sep 2020 20:24:50

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:43', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '621b3123-3578-4ac8-b629-1d97e076b681'	System	09 Sep 2020 20:24:50
User entered 'No (N)'	System	09 Sep 2020 20:24:50

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:46', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '621b3123-3578-4ac8-b629-1d97e076b681'	System	09 Sep 2020 20:24:50
User entered '09 Sep 2020 13:24'	System	09 Sep 2020 20:24:50

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:19', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '60cddbdd-949f-48d2-ad44-4b2897ce9255'	System	04 Sep 2020 00:38:37
User entered 'None (1)'	System	04 Sep 2020 00:38:37

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:24', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '60cddbdd-949f-48d2-ad44-4b2897ce9255'	System	04 Sep 2020 00:38:37
User entered 'No (N)'	System	04 Sep 2020 00:38:37

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:28', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '60cddbdd-949f-48d2-ad44-4b2897ce9255'	System	04 Sep 2020 00:38:37
User entered 'No (N)'	System	04 Sep 2020 00:38:37

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:33', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '60cddbdd-949f-48d2-ad44-4b2897ce9255'	System	04 Sep 2020 00:38:37
User entered 'None (1)'	System	04 Sep 2020 00:38:37

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '60cddbdd-949f-48d2-ad44-4b2897ce9255'	System	04 Sep 2020 00:38:37
User entered '03 Sep 2020 17:38'	System	04 Sep 2020 00:38:37

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 17:29'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 19:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e7a9d6ad-0193-432b-9ed4-79b3a047ab93'	System	04 Sep 2020 05:43:42
User entered 'None (1)'	System	04 Sep 2020 05:43:42

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e7a9d6ad-0193-432b-9ed4-79b3a047ab93'	System	04 Sep 2020 05:43:42
User entered 'Yes (Y)'	System	04 Sep 2020 05:43:42

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:31', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e7a9d6ad-0193-432b-9ed4-79b3a047ab93'	System	04 Sep 2020 05:43:42
User entered '3'	System	04 Sep 2020 05:43:42

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e7a9d6ad-0193-432b-9ed4-79b3a047ab93'	System	04 Sep 2020 05:43:42
User entered 'No (N)'	System	04 Sep 2020 05:43:42

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:35', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e7a9d6ad-0193-432b-9ed4-79b3a047ab93'	System	04 Sep 2020 05:43:42
User entered 'None (1)'	System	04 Sep 2020 05:43:42

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e7a9d6ad-0193-432b-9ed4-79b3a047ab93'	System	04 Sep 2020 05:43:42
User entered '03 Sep 2020 22:43'	System	04 Sep 2020 05:43:42

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 20:54'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 2'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:41', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f2aaf3df-53e6-4003-a84a-e82f86c53699'	System	04 Sep 2020 19:21:59
User entered 'None (1)'	System	04 Sep 2020 19:21:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:45', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f2aaf3df-53e6-4003-a84a-e82f86c53699'	System	04 Sep 2020 19:21:59
User entered 'No (N)'	System	04 Sep 2020 19:21:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:48', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f2aaf3df-53e6-4003-a84a-e82f86c53699'	System	04 Sep 2020 19:21:59
User entered 'No (N)'	System	04 Sep 2020 19:21:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:55', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f2aaf3df-53e6-4003-a84a-e82f86c53699'	System	04 Sep 2020 19:21:59
User entered 'None (1)'	System	04 Sep 2020 19:21:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:21:57', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f2aaf3df-53e6-4003-a84a-e82f86c53699'	System	04 Sep 2020 19:21:59
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 19:21:59

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 3'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:45', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '84b8fbb5-bc3d-425f-a5cd-b5f66a101959'	System	06 Sep 2020 03:42:58
User entered 'None (1)'	System	06 Sep 2020 03:42:58

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:48', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '84b8fbb5-bc3d-425f-a5cd-b5f66a101959'	System	06 Sep 2020 03:42:58
User entered 'No (N)'	System	06 Sep 2020 03:42:58

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:50', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '84b8fbb5-bc3d-425f-a5cd-b5f66a101959'	System	06 Sep 2020 03:42:58
User entered 'No (N)'	System	06 Sep 2020 03:42:58

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:52', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '84b8fbb5-bc3d-425f-a5cd-b5f66a101959'	System	06 Sep 2020 03:42:58
User entered 'None (1)'	System	06 Sep 2020 03:42:58

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:56', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '84b8fbb5-bc3d-425f-a5cd-b5f66a101959'	System	06 Sep 2020 03:42:58
User entered '05 Sep 2020 20:42'	System	06 Sep 2020 03:42:58

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 4'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:46', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '88cd1f97-a274-4f93-8653-ab60ff94f7e3'	System	07 Sep 2020 05:41:57
User entered 'None (1)'	System	07 Sep 2020 05:41:57

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:49', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '88cd1f97-a274-4f93-8653-ab60ff94f7e3'	System	07 Sep 2020 05:41:57
User entered 'No (N)'	System	07 Sep 2020 05:41:57

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '88cd1f97-a274-4f93-8653-ab60ff94f7e3'	System	07 Sep 2020 05:41:57
User entered 'No (N)'	System	07 Sep 2020 05:41:57

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:53', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '88cd1f97-a274-4f93-8653-ab60ff94f7e3'	System	07 Sep 2020 05:41:57
User entered 'None (1)'	System	07 Sep 2020 05:41:57

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:56', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '88cd1f97-a274-4f93-8653-ab60ff94f7e3'	System	07 Sep 2020 05:41:57
User entered '06 Sep 2020 22:41'	System	07 Sep 2020 05:41:57

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 5'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:17', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '19c9cc9d-c1c2-4892-897c-762bd12be738'	System	07 Sep 2020 21:51:27
User entered 'None (1)'	System	07 Sep 2020 21:51:27

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:19', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '19c9cc9d-c1c2-4892-897c-762bd12be738'	System	07 Sep 2020 21:51:27
User entered 'No (N)'	System	07 Sep 2020 21:51:27

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:20', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '19c9cc9d-c1c2-4892-897c-762bd12be738'	System	07 Sep 2020 21:51:27
User entered 'No (N)'	System	07 Sep 2020 21:51:27

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:22', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '19c9cc9d-c1c2-4892-897c-762bd12be738'	System	07 Sep 2020 21:51:27
User entered 'None (1)'	System	07 Sep 2020 21:51:27

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:24', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '19c9cc9d-c1c2-4892-897c-762bd12be738'	System	07 Sep 2020 21:51:27
User entered '07 Sep 2020 14:51'	System	07 Sep 2020 21:51:27

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 6'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:29', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e63dfa7e-338a-4501-8b38-0107a761263b'	System	09 Sep 2020 02:26:39
User entered 'None (1)'	System	09 Sep 2020 02:26:39

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:31', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e63dfa7e-338a-4501-8b38-0107a761263b'	System	09 Sep 2020 02:26:39
User entered 'No (N)'	System	09 Sep 2020 02:26:39

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:32', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e63dfa7e-338a-4501-8b38-0107a761263b'	System	09 Sep 2020 02:26:39
User entered 'No (N)'	System	09 Sep 2020 02:26:39

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:34', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e63dfa7e-338a-4501-8b38-0107a761263b'	System	09 Sep 2020 02:26:39
User entered 'None (1)'	System	09 Sep 2020 02:26:39

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'e63dfa7e-338a-4501-8b38-0107a761263b'	System	09 Sep 2020 02:26:39
User entered '08 Sep 2020 19:26'	System	09 Sep 2020 02:26:39

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 7'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:49', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a990e10-f745-43f9-8759-ffa1a98435cc'	System	09 Sep 2020 20:25:05
User entered 'None (1)'	System	09 Sep 2020 20:25:05

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:53', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a990e10-f745-43f9-8759-ffa1a98435cc'	System	09 Sep 2020 20:25:05
User entered 'No (N)'	System	09 Sep 2020 20:25:05

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:54', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a990e10-f745-43f9-8759-ffa1a98435cc'	System	09 Sep 2020 20:25:05
User entered 'No (N)'	System	09 Sep 2020 20:25:05

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:24:56', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a990e10-f745-43f9-8759-ffa1a98435cc'	System	09 Sep 2020 20:25:05
User entered 'None (1)'	System	09 Sep 2020 20:25:05

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a990e10-f745-43f9-8759-ffa1a98435cc'	System	09 Sep 2020 20:25:05
User entered '09 Sep 2020 13:25'	System	09 Sep 2020 20:25:05

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered 'None (0)'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:49', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered 'None (0)'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:52', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered 'None (0)'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:54', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered 'None (0)'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:56', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered 'None (0)'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:38:58', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered 'None (0)'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:39:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered 'No (N)'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T17:39:03', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'd8ecd82e-f389-4b02-b279-836f6c7356be'	System	04 Sep 2020 00:39:06
User entered '03 Sep 2020 17:39'	System	04 Sep 2020 00:39:06

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 17:29'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 19:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered 'None (0)'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:46', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered 'None (0)'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:49', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered 'None (0)'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered 'None (0)'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:53', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered 'None (0)'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:55', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered 'None (0)'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:57', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered 'No (N)'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-03T22:43:59', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0660a655-00db-4a1b-aaf0-95f190de99c0'	System	04 Sep 2020 05:44:02
User entered '03 Sep 2020 22:43'	System	04 Sep 2020 05:44:02

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '03 Sep 2020 20:54'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 2'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:22:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered 'None (0)'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:22:03', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered 'None (0)'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:22:06', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered 'None (0)'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:22:09', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered 'None (0)'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:22:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered 'None (0)'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:22:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered 'None (0)'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:22:16', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered 'No (N)'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-04T12:23:49', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '28400059-19b2-4e16-b9be-1decaffdd41c'	System	04 Sep 2020 19:23:50
User entered '04 Sep 2020 12:23'	System	04 Sep 2020 19:23:50

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 3'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:42:59', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered 'None (0)'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:43:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered 'None (0)'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:43:02', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered 'None (0)'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:43:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered 'None (0)'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:43:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered 'None (0)'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:43:07', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered 'None (0)'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:43:09', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered 'No (N)'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-05T20:43:12', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '47c6a740-cd48-4944-924a-3c32fed94dec'	System	06 Sep 2020 03:43:14
User entered '05 Sep 2020 20:43'	System	06 Sep 2020 03:43:14

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 4'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:41:59', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered 'None (0)'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:42:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered 'None (0)'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:42:03', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered 'None (0)'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:42:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered 'None (0)'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:42:07', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered 'None (0)'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:42:09', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered 'None (0)'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:42:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered 'No (N)'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-06T22:42:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8a2992ec-2375-4c60-8efb-b67294a75743'	System	07 Sep 2020 05:42:18
User entered '06 Sep 2020 22:42'	System	07 Sep 2020 05:42:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 5'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:26', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a'	System	07 Sep 2020 21:51:38
User entered 'None (0)'	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:28', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a'	System	07 Sep 2020 21:51:38
User entered 'None (0)'	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:29', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a'	System	07 Sep 2020 21:51:38
User entered 'None (0)'	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:30', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a' User entered 'None (0)'	System	07 Sep 2020 21:51:38
	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:31', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a'	System	07 Sep 2020 21:51:38
User entered 'None (0)'	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:32', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a'	System	07 Sep 2020 21:51:38
User entered 'None (0)'	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:33', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a'	System	07 Sep 2020 21:51:38
User entered 'No (N)'	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-07T14:51:36', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'de034e29-3440-4ebd-bb63-b4537887a17a'	System	07 Sep 2020 21:51:38
User entered '07 Sep 2020 14:51'	System	07 Sep 2020 21:51:38

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 6'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:40', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered 'None (0)'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered 'None (0)'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:44', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered 'None (0)'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:46', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered 'None (0)'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:48', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered 'None (0)'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:50', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered 'None (0)'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:52', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered 'No (N)'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-08T19:26:55', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '52a6a933-2602-48a6-9a50-337d28c88f5c'	System	09 Sep 2020 02:26:58
User entered '08 Sep 2020 19:26'	System	09 Sep 2020 02:26:58

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	04 Sep 2020 00:19:24
User entered 'Day 7'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:03', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered 'None (0)'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered 'None (0)'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:05', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered 'None (0)'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:07', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered 'None (0)'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:08', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered 'None (0)'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:10', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered 'None (0)'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:12', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered 'No (N)'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-09-09T13:25:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '55fdb592-6eac-4988-bb9e-45329be9005c'	System	09 Sep 2020 20:25:18
User entered '09 Sep 2020 13:25'	System	09 Sep 2020 20:25:18

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 00:19:24

US3112119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 00:19:24

US3112119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:10:56

US3112119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:31:20
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'updated comment' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 17:21:48
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 21:10:56
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:10:56

US3112119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:10:56

US3112119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'first attempt to contact subject was made on 9/11/2020. Subject returned call on 9/14/2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 17:21:40
	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 21:10:56

US3112119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:11:01

US3112119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	14 Sep 2020 21:11:01

US3112119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	17 Sep 2020 22:26:11

US3112119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '17 Sep 2020'	Karen Mylerberg (b) (4)	17 Sep 2020 22:26:11

US3112119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	17 Sep 2020 22:26:11

US3112119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Karen Mylerberg (b) (4)	17 Sep 2020 22:26:11

US3112119

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	17 Sep 2020 22:26:17

US3112119

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	17 Sep 2020 22:26:17

US3112119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 17:23:11

US3112119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '25 Sep 2020'	Karen Mylerberg (b) (4)	25 Sep 2020 17:23:11

US3112119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	25 Sep 2020 17:23:11

US3112119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 17:23:11

US3112119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 21:02:38

US3112119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	13 Oct 2020 21:02:38

US3112119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 21:03:08

US3112119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Oct 2020'	Natalie Moy (b) (4)	13 Oct 2020 21:03:08

US3112119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	13 Oct 2020 21:03:08

US3112119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'VISIT3'	System	13 Oct 2020 21:03:08

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Oct 2020'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '15:20'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '5 Oct 2020 15:20'	System	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '97.5' F	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '87'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'bpm'	System	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '16'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'breaths/min'	System	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '105'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '80'	Natalie Moy (b) (4)	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'mmHg'	System	13 Oct 2020 21:03:56

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20

US3112119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20

US3112119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'No (N)'	Natalie Moy (b) (4)	13 Oct 2020 21:04:15

US3112119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered empty.	Natalie Moy (b) (4)	13 Oct 2020 21:04:15

US3112119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 21:04:32

US3112119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '5 Oct 2020'	Natalie Moy (b) (4)	13 Oct 2020 21:04:32

US3112119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered '15:50'	Natalie Moy (b) (4)	13 Oct 2020 21:04:32

US3112119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '5 Oct 2020 15:50'	System	13 Oct 2020 21:04:32

US3112119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:25
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 21:04:38

US3112119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered '1'	System	13 Oct 2020 21:04:38

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 64'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-05T10:53:23', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ee644808-27ae-4252-8b2a-58743cb110eb'	System	05 Oct 2020 17:53:39
User entered 'No (N)'	System	05 Oct 2020 17:53:39

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-05T10:53:29', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ee644808-27ae-4252-8b2a-58743cb110eb'	System	05 Oct 2020 17:53:39
User entered 'No (N)'	System	05 Oct 2020 17:53:39

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-05T10:53:33', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ee644808-27ae-4252-8b2a-58743cb110eb' User entered '05 Oct 2020 10:53:33'	System	05 Oct 2020 17:53:39
	System	05 Oct 2020 17:53:39

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 71'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-13T07:16:47', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c410c391-15c6-406e-bc04-5857aa16e0f5'	System	13 Oct 2020 14:17:28
User entered 'No (N)'	System	13 Oct 2020 14:17:28

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-13T07:16:58', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c410c391-15c6-406e-bc04-5857aa16e0f5'	System	13 Oct 2020 14:17:28
User entered 'Yes (Y)'	System	13 Oct 2020 14:17:28

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Please 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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-13T07:17:12', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c410c391-15c6-406e-bc04-5857aa16e0f5'	System	13 Oct 2020 14:17:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Oct 2020 14:17:28

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-13T07:17:17', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'c410c391-15c6-406e-bc04-5857aa16e0f5'	System	13 Oct 2020 14:17:28
User entered '13 Oct 2020 07:17:17'	System	13 Oct 2020 14:17:28

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 78'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-23T04:18:56', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '402e833d-3703-45ea-b54a-08f373fe36ef'	System	22 Oct 2020 22:19:11
User entered 'No (N)'	System	22 Oct 2020 22:19:11

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-23T04:19:04', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '402e833d-3703-45ea-b54a-08f373fe36ef'	System	22 Oct 2020 22:19:11
User entered 'No (N)'	System	22 Oct 2020 22:19:11

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-10-23T04:19:08', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '402e833d-3703-45ea-b54a-08f373fe36ef'	System	22 Oct 2020 22:19:11
User entered '23 Oct 2020 04:19:08'	System	22 Oct 2020 22:19:11

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 92'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-02T07:20:50', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '25956d5b-701b-4502-95db-9bc543ed32fd'	System	02 Nov 2020 01:21:03
User entered 'No (N)'	System	02 Nov 2020 01:21:03

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Have you been exposed to someone with 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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-02T07:20:58', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '25956d5b-701b-4502-95db-9bc543ed32fd'	System	02 Nov 2020 01:21:03
User entered 'No (N)'	System	02 Nov 2020 01:21:03

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-02T07:21:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '25956d5b-701b-4502-95db-9bc543ed32fd'	System	02 Nov 2020 01:21:03
User entered '02 Nov 2020 07:21:00'	System	02 Nov 2020 01:21:03

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 99'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-09T17:08:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dd1232ba-a281-4b54-9128-2eedd3b3c4a0'	System	10 Nov 2020 01:08:44
User entered 'No (N)'	System	10 Nov 2020 01:08:44

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Have you been exposed to someone with 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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-09T17:08:40', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dd1232ba-a281-4b54-9128-2eedd3b3c4a0'	System	10 Nov 2020 01:08:44
User entered 'No (N)'	System	10 Nov 2020 01:08:44

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-09T17:08:42', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'dd1232ba-a281-4b54-9128-2eedd3b3c4a0'	System	10 Nov 2020 01:08:44
User entered '09 Nov 2020 17:08:42'	System	10 Nov 2020 01:08:44

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered 'Day 106'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-18T22:12:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f1a3ba16-b224-4fa8-922f-47cad87463fa'	System	19 Nov 2020 06:12:30
User entered 'No (N)'	System	19 Nov 2020 06:12:30

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-18T22:12:24', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f1a3ba16-b224-4fa8-922f-47cad87463fa'	System	19 Nov 2020 06:12:30
User entered 'No (N)'	System	19 Nov 2020 06:12:30

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-11-18T22:12:27', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'f1a3ba16-b224-4fa8-922f-47cad87463fa' User entered '18 Nov 2020 22:12:27'	System	19 Nov 2020 06:12:30
	System	19 Nov 2020 06:12:30

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 23:49:35

US3112119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:26
Data entry locked.	System	05 Aug 2020 23:49:35
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 23:49:35

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2020-12-01T00:01:52', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '781a7310-76ee-4c78-9daa-f30ef8c724cf'	System	01 Dec 2020 08:02:11
User entered 'No (N)'	System	01 Dec 2020 08:02:11

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2020-12-01T00:02:03', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '781a7310-76ee-4c78-9daa-f30ef8c724cf'	System	01 Dec 2020 08:02:11
User entered 'No (N)'	System	01 Dec 2020 08:02:11

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-12-01T00:02:08', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '781a7310-76ee-4c78-9daa-f30ef8c724cf' User entered '01 Dec 2020 00:02:08'	System	01 Dec 2020 08:02:11
	System	01 Dec 2020 08:02:11

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2020-12-04T17:20:30', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '950bfd11-f682-4f02-b5fe-79f54daef16c'	System	05 Dec 2020 01:20:43
User entered 'No (N)'	System	05 Dec 2020 01:20:43

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2020-12-04T17:20:35', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '950bfd11-f682-4f02-b5fe-79f54daef16c'	System	05 Dec 2020 01:20:43
User entered 'No (N)'	System	05 Dec 2020 01:20:43

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-12-04T17:20:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '950bfd11-f682-4f02-b5fe-79f54daef16c' User entered '04 Dec 2020 17:20:38'	System	05 Dec 2020 01:20:43
	System	05 Dec 2020 01:20:43

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2020-12-11T09:21:48', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '4805e81d-a256-4bf5-af6e-bf31a3e4c230'	System	11 Dec 2020 17:21:59
User entered 'No (N)'	System	11 Dec 2020 17:21:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2020-12-11T09:21:51', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '4805e81d-a256-4bf5-af6e-bf31a3e4c230'	System	11 Dec 2020 17:21:59
User entered 'No (N)'	System	11 Dec 2020 17:21:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-12-11T09:21:54', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '4805e81d-a256-4bf5-af6e-bf31a3e4c230'	System	11 Dec 2020 17:21:59
User entered '11 Dec 2020 09:21:54'	System	11 Dec 2020 17:21:59

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2020-12-18T16:25:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '62354dc7-5a9f-4458-9bc2-9be9f38c9adb'	System	19 Dec 2020 00:25:27
User entered 'No (N)'	System	19 Dec 2020 00:25:27

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2020-12-18T16:25:21', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '62354dc7-5a9f-4458-9bc2-9be9f38c9adb'	System	19 Dec 2020 00:25:27
User entered 'No (N)'	System	19 Dec 2020 00:25:27

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-12-18T16:25:23', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '62354dc7-5a9f-4458-9bc2-9be9f38c9adb' User entered '18 Dec 2020 16:25:23'	System	19 Dec 2020 00:25:27

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2020-12-26T22:32:28', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '27af7625-0a4f-4e39-bce4-1a9436329a94'	System	27 Dec 2020 06:32:41
User entered 'No (N)'	System	27 Dec 2020 06:32:41

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2020-12-26T22:32:31', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '27af7625-0a4f-4e39-bce4-1a9436329a94'	System	27 Dec 2020 06:32:41
User entered 'No (N)'	System	27 Dec 2020 06:32:41

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2020-12-26T22:32:38', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '27af7625-0a4f-4e39-bce4-1a9436329a94'	System	27 Dec 2020 06:32:41
User entered '26 Dec 2020 22:32:38'	System	27 Dec 2020 06:32:41

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-01-05T13:40:31', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fbcab5d-96a7-4139-9817-3b1e4bb0d382'	System	05 Jan 2021 21:40:58
User entered 'No (N)'	System	05 Jan 2021 21:40:58

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-01-05T13:40:40', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fbcab5d-96a7-4139-9817-3b1e4bb0d382'	System	05 Jan 2021 21:40:58
User entered 'Yes (Y)'	System	05 Jan 2021 21:40:58

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-01-05T13:40:44', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fbcab5d-96a7-4139-9817-3b1e4bb0d382'	System	05 Jan 2021 21:40:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Jan 2021 21:40:58

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-01-05T13:40:47', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fbcab5d-96a7-4139-9817-3b1e4bb0d382'	System	05 Jan 2021 21:40:58
User entered '05 Jan 2021 13:40:47'	System	05 Jan 2021 21:40:58

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-01-08T08:04:46', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'eced7c20-5b63-4e4c-8707-c33c4aae19b5'	System	08 Jan 2021 16:04:58
User entered 'No (N)'	System	08 Jan 2021 16:04:58

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-01-08T08:04:49', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'eced7c20-5b63-4e4c-8707-c33c4aae19b5'	System	08 Jan 2021 16:04:58
User entered 'No (N)'	System	08 Jan 2021 16:04:58

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-01-08T08:04:52', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'eced7c20-5b63-4e4c-8707-c33c4aae19b5'	System	08 Jan 2021 16:04:58
User entered '08 Jan 2021 08:04:52'	System	08 Jan 2021 16:04:58

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-01-18T07:36:59', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '712ac28e-a15d-44f6-9222-16f5dd4dfac7'	System	18 Jan 2021 15:37:07
User entered 'No (N)'	System	18 Jan 2021 15:37:07

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-01-18T07:37:01', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '712ac28e-a15d-44f6-9222-16f5dd4dfac7'	System	18 Jan 2021 15:37:07
User entered 'No (N)'	System	18 Jan 2021 15:37:07

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-01-18T07:37:03', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '712ac28e-a15d-44f6-9222-16f5dd4dfac7'	System	18 Jan 2021 15:37:07
User entered '18 Jan 2021 07:37:03'	System	18 Jan 2021 15:37:07

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-01-22T16:00:35', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '475cefb7-1616-4cfc-98d1-04a91e363e84'	System	23 Jan 2021 00:00:56
User entered 'No (N)'	System	23 Jan 2021 00:00:56

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-01-22T16:00:37', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '475cefb7-1616-4cfc-98d1-04a91e363e84'	System	23 Jan 2021 00:00:56
User entered 'No (N)'	System	23 Jan 2021 00:00:56

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-01-22T16:00:40', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '475cefb7-1616-4cfc-98d1-04a91e363e84' User entered '22 Jan 2021 16:00:40'	System	23 Jan 2021 00:00:56
	System	23 Jan 2021 00:00:56

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-02-02T09:10:32', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '9029a67e-bb2b-46a5-8e0b-cfb7d49b2311'	System	02 Feb 2021 17:13:48
User entered 'No (N)'	System	02 Feb 2021 17:13:48

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-02-02T09:10:34', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '9029a67e-bb2b-46a5-8e0b-cfb7d49b2311'	System	02 Feb 2021 17:13:48
User entered 'No (N)'	System	02 Feb 2021 17:13:48

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-02-02T09:10:37', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '9029a67e-bb2b-46a5-8e0b-cfb7d49b2311'	System	02 Feb 2021 17:13:48
User entered '02 Feb 2021 09:10:37'	System	02 Feb 2021 17:13:48

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-02-09T09:51:08', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '5b170fff-17ef-42c4-be28-115dfa4d1a10'	System	09 Feb 2021 17:51:17
User entered 'No (N)'	System	09 Feb 2021 17:51:17

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-02-09T09:51:11', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '5b170fff-17ef-42c4-be28-115dfa4d1a10'	System	09 Feb 2021 17:51:17
User entered 'No (N)'	System	09 Feb 2021 17:51:17

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-02-09T09:51:14', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '5b170fff-17ef-42c4-be28-115dfa4d1a10'	System	09 Feb 2021 17:51:17
User entered '09 Feb 2021 09:51:14'	System	09 Feb 2021 17:51:17

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-02-20T06:28:08', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8d1eac97-088e-4185-9bd7-8f2574a44d98'	System	20 Feb 2021 14:28:16
User entered 'No (N)'	System	20 Feb 2021 14:28:16

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-02-20T06:28:10', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8d1eac97-088e-4185-9bd7-8f2574a44d98'	System	20 Feb 2021 14:28:16
User entered 'No (N)'	System	20 Feb 2021 14:28:16

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-02-20T06:28:12', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '8d1eac97-088e-4185-9bd7-8f2574a44d98'	System	20 Feb 2021 14:28:16
User entered '20 Feb 2021 06:28:12'	System	20 Feb 2021 14:28:16

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-02-26T17:38:42-08:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ce58823f-5b64-4292-87a7-79935ea7bfc7'	System	27 Feb 2021 01:38:51
User entered 'No (N)'	System	27 Feb 2021 01:38:51

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-02-26T17:38:43-08:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ce58823f-5b64-4292-87a7-79935ea7bfc7'	System	27 Feb 2021 01:38:51
User entered 'No (N)'	System	27 Feb 2021 01:38:51

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-02-26T17:38:45-08:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ce58823f-5b64-4292-87a7-79935ea7bfc7'	System	27 Feb 2021 01:38:51
User entered '26 Feb 2021 17:38:45'	System	27 Feb 2021 01:38:51

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-03-14T23:38:57-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ce3d20ed-d471-467c-9299-6d1a99088ab4'	System	15 Mar 2021 06:39:06
User entered 'No (N)'	System	15 Mar 2021 06:39:06

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-03-14T23:38:58-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ce3d20ed-d471-467c-9299-6d1a99088ab4'	System	15 Mar 2021 06:39:06
User entered 'No (N)'	System	15 Mar 2021 06:39:06

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-03-14T23:39:01-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'ce3d20ed-d471-467c-9299-6d1a99088ab4' User entered '14 Mar 2021 23:39:01'	System	15 Mar 2021 06:39:06
	System	15 Mar 2021 06:39:06

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-03-23T20:08:04-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fd2495b-6165-49d4-9804-e17a90f3783c' User entered 'No (N)'	System	24 Mar 2021 03:08:11
	System	24 Mar 2021 03:08:11

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-03-23T20:08:06-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fd2495b-6165-49d4-9804-e17a90f3783c'	System	24 Mar 2021 03:08:11
User entered 'No (N)'	System	24 Mar 2021 03:08:11

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-03-23T20:08:09-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '2fd2495b-6165-49d4-9804-e17a90f3783c'	System	24 Mar 2021 03:08:11
User entered '23 Mar 2021 20:08:09'	System	24 Mar 2021 03:08:11

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-04-02T07:20:52-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a80c173d-dd88-4537-a1ef-a42051f2df48'	System	02 Apr 2021 14:21:40
User entered 'Yes (Y)'	System	02 Apr 2021 14:21:40

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-04-02T07:20:57-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a80c173d-dd88-4537-a1ef-a42051f2df48'	System	02 Apr 2021 14:21:40
User entered 'No (N)'	System	02 Apr 2021 14:21:40

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-04-02T07:21:01-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a80c173d-dd88-4537-a1ef-a42051f2df48'	System	02 Apr 2021 14:21:40
User entered 'No (N)'	System	02 Apr 2021 14:21:40

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-04-02T07:21:15-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a80c173d-dd88-4537-a1ef-a42051f2df48'	System	02 Apr 2021 14:21:40
User entered 'Yes (Y)'	System	02 Apr 2021 14:21:40

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-04-02T07:21:25-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a80c173d-dd88-4537-a1ef-a42051f2df48'	System	02 Apr 2021 14:21:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Apr 2021 14:21:40

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-04-02T07:21:28-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: 'a80c173d-dd88-4537-a1ef-a42051f2df48'	System	02 Apr 2021 14:21:40
User entered '02 Apr 2021 07:21:28'	System	02 Apr 2021 14:21:40

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-04-13T13:22:24-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '96e14ad0-77d2-4edb-8c95-96ed204293a9'	System	13 Apr 2021 20:22:50
User entered 'No (N)'	System	13 Apr 2021 20:22:50

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-04-13T13:22:38-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '96e14ad0-77d2-4edb-8c95-96ed204293a9'	System	13 Apr 2021 20:22:50
User entered 'No (N)'	System	13 Apr 2021 20:22:50

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-04-13T13:22:43-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '96e14ad0-77d2-4edb-8c95-96ed204293a9' User entered '13 Apr 2021 13:22:43'	System	13 Apr 2021 20:22:50
	System	13 Apr 2021 20:22:50

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-04-25T12:48:08-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '3b8b3a36-1f5a-4045-8630-e427ad01f5a7'	System	25 Apr 2021 19:48:19
User entered 'No (N)'	System	25 Apr 2021 19:48:19

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-04-25T12:48:12-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '3b8b3a36-1f5a-4045-8630-e427ad01f5a7'	System	25 Apr 2021 19:48:19
User entered 'No (N)'	System	25 Apr 2021 19:48:19

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-04-25T12:48:14-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '3b8b3a36-1f5a-4045-8630-e427ad01f5a7'	System	25 Apr 2021 19:48:19
User entered '25 Apr 2021 12:48:14'	System	25 Apr 2021 19:48:19

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[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 (c6eae48b4d0727f6)', Time: '2021-04-30T06:25:16-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0b91aabe-0bef-4d27-bafc-7656c2d3f62e' User entered 'No (N)'	System	30 Apr 2021 13:25:29

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

Have you been exposed to someone with 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 (c6eae48b4d0727f6)', Time: '2021-04-30T06:25:20-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0b91aabe-0bef-4d27-bafc-7656c2d3f62e'	System	30 Apr 2021 13:25:29
User entered 'No (N)'	System	30 Apr 2021 13:25:29

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-04-30T06:25:26-07:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '0b91aabe-0bef-4d27-bafc-7656c2d3f62e'	System	30 Apr 2021 13:25:29
User entered '30 Apr 2021 06:25:26'	System	30 Apr 2021 13:25:29

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 14:01:09

US3112119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:01:09
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 14:01:09

US3112119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:10:35

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)	29 Apr 2021 19:47:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-03-01T15:30:26-08:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '97516090-429f-44a5-972a-0ded99329a20'	System	01 Mar 2021 23:30:42
User entered 'No (N)'	System	01 Mar 2021 23:30:42

US3112119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:10:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:47:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6eae48b4d0727f6)', Time: '2021-03-01T15:30:40-08:00', User OID: 'PatientReportedOutcome (US3112119)', ODM File OID: '97516090-429f-44a5-972a-0ded99329a20' User entered '01 Mar 2021 15:30:40'	System	01 Mar 2021 23:30:42
	System	01 Mar 2021 23:30:42

US3112119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:03
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:36:40

US3112119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:03
User entered '29 Oct 2020'	Matthew Musikanth (b) (4)	29 Oct 2020 16:36:40

US3112119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:03
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:36:40

US3112119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:03
User entered empty.	Matthew Musikanth (b) (4)	29 Oct 2020 16:36:40

US3112119

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:03
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:36:44

US3112119

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:20
User entered 'I'	System	29 Oct 2020 16:36:44

US3112119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Dec 2020 23:24:36

US3112119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '01 Dec 2020'	Matthew Musikanth (b) (4)	01 Dec 2020 23:24:36

US3112119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	01 Dec 2020 23:24:36

US3112119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Matthew Musikanth (b) (4)	01 Dec 2020 23:24:36

US3112119

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Dec 2020 23:24:43

US3112119

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'I'	System	01 Dec 2020 23:24:43

US3112119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	31 Dec 2020 23:33:20

US3112119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '31 Dec 2020'	Karen Mylerberg (b) (4)	31 Dec 2020 23:33:20

US3112119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	31 Dec 2020 23:33:20

US3112119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	31 Dec 2020 23:33:20

US3112119

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	31 Dec 2020 23:33:25

US3112119

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'I'	System	31 Dec 2020 23:33:25

US3112119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	02 Feb 2021 19:27:57

US3112119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '2 Feb 2021'	Brenda Grande (b) (4)	02 Feb 2021 19:27:57

US3112119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	02 Feb 2021 19:27:57

US3112119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Brenda Grande (b) (4)	02 Feb 2021 19:27:57

US3112119

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	02 Feb 2021 19:28:01

US3112119

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'I'	System	02 Feb 2021 19:28:01

US3112119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Mar 2021 00:12:05

US3112119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '2 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:22:05
User entered '4 Mar 2021'	Natalie Moy (b) (4)	05 Mar 2021 00:12:05

US3112119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	05 Mar 2021 00:12:05

US3112119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'VISIT4'	System	05 Mar 2021 00:12:05

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Mar 2021 18:22:05
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	30 Mar 2021 18:22:05
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Mar 2021 18:21:40
User entered '02 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:57'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered '02 Mar 2021 15:57'	System	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '98.9' F	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '87'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'bpm'	System	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'breaths/min'	System	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '121'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'mmHg'	System	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '85'	(b) (4), (b) (6)	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'mmHg'	System	30 Mar 2021 18:21:40

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58

US3112119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58

US3112119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Natalie Moy (b) (4)	05 Mar 2021 00:12:20

US3112119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Mar 2021 00:12:20

US3112119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Natalie Moy (b) (4)	05 Mar 2021 00:12:24

US3112119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Mar 2021 00:12:24

US3112119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Mar 2021 00:12:24

US3112119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered empty.	System	05 Mar 2021 00:12:24

US3112119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Mar 2021 00:12:27

US3112119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:06:58
User entered 'I'	System	05 Mar 2021 00:12:27

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:41:59

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:41:59

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4)	08 Jan 2021 18:41:59

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 18:41:59

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '06 Jan 2021' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	09 Feb 2021 18:34:59
User entered '24 Dec 2020'	Brenda Grande (b) (4)	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:37:58

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:37:58

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4)	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:26:45
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4)	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:26:45
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4)	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '1'	System	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '1'	System	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered empty.	System	08 Jan 2021 18:46:28
DataPoint set to visible.	System	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered empty.	System	08 Jan 2021 18:46:28
DataPoint set to visible.	System	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:15'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '7 Jan 2021 15:15'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '98.6' F	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (Oral)'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '89'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'bpm'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'breaths/min'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '124'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '80'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered empty.	System	08 Jan 2021 18:46:28
DataPoint set to visible.	System	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16:21'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '7 Jan 2021 16:21'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '98.8' F	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (Oral)'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '88'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'bpm'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'breaths/min'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '132'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '88'	Brenda Grande (b) (4)	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	08 Jan 2021 18:46:28

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:46:55

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:46:55

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Brenda Grande (b) (4)	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Brenda Grande (b) (4)	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mRNA-1273'	System	08 Jan 2021 18:47:51
DataPoint set to visible.	System	08 Jan 2021 18:42:24

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:50'	Brenda Grande (b) (4)	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '7 Jan 2021 15:50'	System	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Left Arm (LEFT ARM)'	Brenda Grande (b) (4)	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'ONCE'	System	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 18:47:51

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:48:09

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:48:09

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:26'	Brenda Grande (b) (4)	08 Jan 2021 18:48:09

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '7 Jan 2021 15:26'	System	08 Jan 2021 18:48:09

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:48:22

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 18:48:22

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:21'	Brenda Grande (b) (4)	08 Jan 2021 18:48:22

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:10:35

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '7 Jan 2021 15:21'	System	08 Jan 2021 18:48:22

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:48:25

US3112119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '1'	System	08 Jan 2021 18:48:25

US3112119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	15 Jan 2021 17:24:54

US3112119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '14 Jan 2021'	Brenda Grande (b) (4)	15 Jan 2021 17:24:54

US3112119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	15 Jan 2021 17:24:54

US3112119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Brenda Grande (b) (4)	15 Jan 2021 17:24:54

US3112119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	15 Jan 2021 17:25:01

US3112119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'I'	System	15 Jan 2021 17:25:01

US3112119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '1'	System	15 Jan 2021 17:25:01
DataPoint set to visible.	System	15 Jan 2021 17:25:01

US3112119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Feb 2021 00:51:24

US3112119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '4 Feb 2021'	Natalie Moy (b) (4)	05 Feb 2021 00:51:24

US3112119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	05 Feb 2021 00:51:24

US3112119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'OLD29'	System	05 Feb 2021 00:51:24

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '4 Feb 2021'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:06'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '4 Feb 2021 15:06'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '98.7' F	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '91'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'bpm'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'breaths/min'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '119'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '83'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '4 Feb 2021'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16:01'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '4 Feb 2021 16:01'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '98.1' F	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '84'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'bpm'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'breaths/min'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '114'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '80'	Natalie Moy (b) (4)	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	05 Feb 2021 00:52:38

US3112119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Feb 2021 00:52:54

US3112119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '4 Feb 2021'	Natalie Moy (b) (4)	05 Feb 2021 00:52:54

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mRNA-1273'	System	05 Feb 2021 00:53:14
DataPoint set to visible.	System	15 Jan 2021 17:25:01

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '4 Feb 2021'	Natalie Moy (b) (4)	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:30'	Natalie Moy (b) (4)	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '4 Feb 2021 15:30'	System	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4)	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'ONCE'	System	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 00:53:14

US3112119

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Feb 2021 00:53:19

US3112119

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'I'	System	05 Feb 2021 00:53:19

US3112119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	11 Feb 2021 22:54:50

US3112119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '11 Feb 2021'	Brenda Grande (b) (4)	11 Feb 2021 22:54:50

US3112119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	11 Feb 2021 22:54:50

US3112119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Brenda Grande (b) (4)	11 Feb 2021 22:54:50

US3112119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Brenda Grande (b) (4)	11 Feb 2021 22:54:56

US3112119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'I'	System	11 Feb 2021 22:54:56

US3112119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Mar 2021 00:12:36

US3112119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '2 Mar 2021' reason for change: Data Entry Error	Brenda Grande (b) (4)	25 Mar 2021 15:51:15
User entered '4 Mar 2021'	Natalie Moy (b) (4)	05 Mar 2021 00:12:36

US3112119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	05 Mar 2021 00:12:36

US3112119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'OLD57'	System	05 Mar 2021 00:12:36

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Mar 2021 15:51:20
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	25 Mar 2021 15:51:20
User entered '2 Mar 2021' reason for change: Data Entry Error	Brenda Grande (b) (4)	25 Mar 2021 15:51:20
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Mar 2021 15:51:15
User entered '4 Mar 2021'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '15:57'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '2 Mar 2021 15:57'	System	25 Mar 2021 15:51:20
User entered '4 Mar 2021 15:57'	System	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '98.9' F	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '87'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'bpm'	System	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'breaths/min'	System	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '121'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '85'	Natalie Moy (b) (4)	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered 'mmHg'	System	05 Mar 2021 00:13:04

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57

US3112119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57

US3112119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Natalie Moy (b) (4)	05 Mar 2021 00:13:11

US3112119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Natalie Moy (b) (4)	05 Mar 2021 00:13:11

US3112119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Natalie Moy (b) (4)	05 Mar 2021 00:13:17

US3112119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User closed query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as in PPD GCL, it is recorded as collected on "02 MAR 2021", however here in EDC, it is recorded as collected on "04 MAR 2021". Please confirm the correct sample collection date in the response, and then please update the correct date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:19:18
Query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as in PPD GCL, it is recorded as collected on "02 MAR 2021", however here in EDC, it is recorded as collected on "04 MAR 2021". Please confirm the correct sample collection date in the response, and then please update the correct date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' answered with 'updated ' (Site from DM).	Brenda Grande (b) (4)	25 Mar 2021 15:51:31
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Mar 2021 15:51:27
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		25 Mar 2021 15:51:27
User entered '2 Mar 2021' reason for change: Data Entry Error	Brenda Grande (b) (4)	25 Mar 2021 15:51:27
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Mar 2021 15:51:15

US3112119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as in PPD GCL, it is recorded as collected on "02 MAR 2021", however here in EDC, it is recorded as collected on "04 MAR 2021". Please confirm the correct sample collection date in the response, and then please update the correct date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM). User entered '4 Mar 2021'	(b) (4), (b) (6)	20 Mar 2021 15:33:56
	Natalie Moy (b) (4)	05 Mar 2021 00:13:17
	(b) (4)	

US3112119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '16:06' reason for change: Data Entry Error	Natalie Moy (b) (4)	05 Mar 2021 00:13:25
User entered '14:06'	Natalie Moy (b) (4)	05 Mar 2021 00:13:17

US3112119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:57
User entered '2 Mar 2021 16:06'	System	25 Mar 2021 15:51:27
User entered '4 Mar 2021 16:06'	System	05 Mar 2021 00:13:25
User entered '4 Mar 2021 14:06'	System	05 Mar 2021 00:13:17

US3112119

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:10:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:40
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:29
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Jan 2021 18:50:42

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:33
User entered 'USA-US062-2021-mRNA-1273-P301000015'	System	05 Apr 2021 16:48:09
User entered 'New'	(b) (4), (b) (6)	05 Apr 2021 16:48:09

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 10:54:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 10:54:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:40:18
Data point term sent to Coder	System	13 Apr 2021 22:38:14
DataPoint Un-verified.	Matthew Musikanth	13 Apr 2021 22:37:41
	(b) (4)	
Coding entries removed.	Matthew Musikanth	13 Apr 2021 22:37:41
	(b) (4)	
Signature has been broken.	Matthew Musikanth	13 Apr 2021 22:37:41
	(b) (4)	
User entered 'CHOLECYSTITIS secondary to cholelithiasis' reason for change: Data Entry Error	Matthew Musikanth	13 Apr 2021 22:37:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 15:37:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 15:37:41
Data point term sent to Coder	System	07 Apr 2021 15:36:53
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 15:36:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 15:36:33
	(b) (4)	

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'CDM Coding, please split the term (CHOLECYSTITIS SECONDARY TO CHOLELITHIASIS) into separate records, as 'CHOLECYSTITIS' and 'CHOLELITHIASIS' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	System	07 Apr 2021 15:36:12
Query 'CDM Coding, please split the term (CHOLECYSTITIS SECONDARY TO CHOLELITHIASIS) into separate records, as 'CHOLECYSTITIS' and 'CHOLELITHIASIS' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'updated' (Site from System).	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 15:36:12
Data point term sent to Coder	System	07 Apr 2021 15:35:51
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 15:35:42
User entered 'CHOLECYSTITIS' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 15:35:42
User opened query 'CDM Coding, please split the term (CHOLECYSTITIS SECONDARY TO CHOLELITHIASIS) into separate records, as 'CHOLECYSTITIS' and 'CHOLELITHIASIS' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	Coder Import (b) (4) (b) (4)	07 Apr 2021 06:47:25
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:00:19
Data point term sent to Coder	System	02 Apr 2021 16:18:55
User entered 'Cholecystitis secondary to cholelithiasis'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'No (N)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'No (N)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
Signature has been broken.	Matthew Musikanth	13 Apr 2021 21:46:34
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Matthew Musikanth	13 Apr 2021 21:46:34
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '31 Mar 2021'	Matthew Musikanth	02 Apr 2021 16:18:43
	(b) (4)	

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered empty.	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:12:24
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	09 Apr 2021 16:31:56
Signature has been broken.	Matthew Musikanth (b) (4)	09 Apr 2021 16:30:52
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	09 Apr 2021 16:30:52
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:42:36
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
Signature has been broken.	Matthew Musikanth	09 Apr 2021 16:30:52
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Matthew Musikanth	09 Apr 2021 16:30:52
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered empty.	Matthew Musikanth	02 Apr 2021 16:18:43
	(b) (4)	

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:12:29
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	09 Apr 2021 16:32:22
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:42:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered empty.	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '0'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '0'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:13:59
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Discharge Summary Sent' (Site from Safety).	Matthew Musikanth (b) (4)	16 Apr 2021 16:42:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:42:28
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 10:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Discharge date missing as patient is still admitted at time of report. ' (Site from System).	Matthew Musikanth (b) (4)	02 Apr 2021 16:19:02

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered 'I'	System	02 Apr 2021 16:18:43
	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
Signature has been broken.	Matthew Musikanth	13 Apr 2021 21:46:34
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Matthew Musikanth	13 Apr 2021 21:46:34
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '31 Mar 2021'	Matthew Musikanth	02 Apr 2021 16:18:43
	(b) (4)	

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:12:37
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	09 Apr 2021 16:32:38
Signature has been broken.	Matthew Musikanth (b) (4)	09 Apr 2021 16:30:52
User entered '02 Apr 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	09 Apr 2021 16:30:52
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:40:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered empty.	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'No (N)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered empty.	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '0'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '0'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '0'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
Signature has been broken.	Brenda Grande (b) (4)	13 Apr 2021 23:05:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '0'	Matthew Musikanth	02 Apr 2021 16:18:43
	(b) (4)	

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered '0'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'I'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
Signature has been broken.	Matthew Musikanth	09 Apr 2021 16:30:52
	(b) (4)	
User entered 'Recovered/Resolved	Matthew Musikanth	09 Apr 2021 16:30:52
(RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error		
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'Not Recovered/Not Resolved (NOT	Matthew Musikanth	02 Apr 2021 16:18:43
RECOVERED/NOT RESOLVED)'	(b) (4)	

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered empty.	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'IQVIA Medical query: Please provide a description of the evolution of the disease leading to the diagnosis of cholecystitis, including signs/symptoms, date of onset, diagnostic evaluations, and clinical course.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:46:32
Query 'IQVIA Medical query: Please provide a description of the evolution of the disease leading to the diagnosis of cholecystitis, including signs/symptoms, date of onset, diagnostic evaluations, and clinical course.' answered with 'Patient had an unprecedented episode of abdominal pain and discomfort in Aug2020, as documented with MAAE of cholelithiasis. Patient was seen by HCP who dx cholelithiasis, pain subsided and no medical intervention completed at time of cholelithiasis dx as severity and assessment did not indicate the need. Patient experienced another episode of extreme abdominal pain on early morning 01Apr2021 which made the subject visit the hospital, medical history of cholelithiasis and diagnostics completed at the hospital suggested cholecystitis. Patient underwent cholecystectomy same day on 01Apr2021. Patient only ever had two major episodes of abdominal pain both leading to dx of cholelithiasis and cholecystitis respectfully. No reported events in between the two. ' (Site from Safety).	Matthew Musikanth (b) (4)	20 Apr 2021 22:45:35
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:58:29
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:58:23

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'IQVIA Medical query: Please provide a description of the evolution of the disease leading to the diagnosis of cholecystitis, including signs/symptoms, date of onset, diagnostic evaluations, and clinical course.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:55:47
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:55:40
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:55:33
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:14:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:14:15
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Con procedure and con medications to be updated. ' (Site from Safety).	Matthew Musikanth (b) (4)	16 Apr 2021 16:43:33

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Pt. had negative COVID-19 test ' (Site from Safety). DataPoint Verified.	Matthew Musikanth (b) (4)	16 Apr 2021 16:38:48
	(b) (4), (b) (6)	13 Apr 2021 22:25:51
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:42:49
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:39:59
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:19
User entered 'pt. with history of cholelithiasis. Diagnosis following study enrollment. pt. now admitted to hospital with new cholecystitis. Surgery being pursued for evolution of disease. Will request medical records and follow up.'	Matthew Musikanth (b) (4)	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:10:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 16:18:43

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 22:21:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 22:21:29
Data point term sent to Coder	System	13 Apr 2021 22:21:03
User entered 'cholelithiasis'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '31 Aug 2020'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User entered empty.	System	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '01 Apr 2021'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User entered empty.	System	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered '0'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'l'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:26:38
User entered empty.	Matthew Musikanth (b) (4)	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User entered '0'	System	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31
User entered 'I'	System	13 Apr 2021 22:20:52

US3112119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:10:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:47:31

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:10:35

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:38:50

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:43:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:43:21
Data point term sent to Coder	System	10 Aug 2020 14:41:22
User entered 'Metformin'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:49:09
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:12
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:23:28
User entered 'Diabetes type 2'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 18:18:47
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
Signature has been broken.	Brenda Grande (b) (4)	13 Apr 2021 23:05:37
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '1000'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'mg (mg)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'twice daily (BID)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:32:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:41:16
User entered 'un UNK 1999'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:41:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Aug 2020 14:41:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:41:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:41:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:48:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:48:42
Data point term sent to Coder	System	10 Aug 2020 14:45:33
User entered 'Trulicity'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:49:14
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	17 Sep 2020 22:28:04
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:23:37
User entered 'Diabetes Type 2'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 23:29:45
User entered '1.8' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:29:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0.75'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'mg (mg)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'every week (QS)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:32:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:45:09
User entered 'UN UNK 2019'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:45:09
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:45:09

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:45:09

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	10 Aug 2020 14:45:09

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:49:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:49:16
Data point term sent to Coder	System	10 Aug 2020 14:46:35
User entered 'Jardiance'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:49:20
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	17 Sep 2020 22:28:16
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:23:46
User entered 'Diabetes Type 2'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '25'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'mg (mg)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'once daily (QD)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:33:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:46:16
User entered 'UN May 2020'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:46:16
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:46:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:46:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:46:16

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN, PRODUCTSYNONYM: DIOVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:52:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:52:14
Data point term sent to Coder	System	10 Aug 2020 14:49:44
User entered 'Diovan'	Karen Mylerberg (b) (4) (b) (4)	10 Aug 2020 14:48:50

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:49:32
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	17 Sep 2020 22:28:28
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:23:57
User entered 'Hypertension'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '160'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'mg (mg)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'once daily (QD)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:33:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:48:50
User entered 'UN UNK 1999'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:48:50
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:48:50

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:48:50

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:48:50

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:53:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:53:11
Data point term sent to Coder	System	10 Aug 2020 14:50:45
User entered 'Vitamin D'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Health Supplement'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '5000'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'IU (IU)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'other (OTHER)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'three times per week'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:33:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:50:04
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:50:04
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:50:04

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:50:04

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:50:04

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:59:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:59:39
Data point term sent to Coder	System	10 Aug 2020 14:55:58
User entered 'Vitamin C'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Health Supplement'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '1000'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'mg (mg)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'other (OTHER)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '3 times per week'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:33:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:55:40
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:55:40
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:55:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:55:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:55:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
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)	11 Aug 2020 11:17:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 11:17:21
Data point term sent to Coder	System	10 Aug 2020 14:59:04
User entered 'Vitamin B12'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Health Supplement'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '5000'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'IU (IU)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'other (OTHER)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'twice per week'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Other (OTHER)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'sublingual'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:33:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:58:35
User entered 'UN UNK 2018'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Aug 2020 14:58:35
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:58:35

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:58:35

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 14:58:35

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
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)	29 Oct 2020 16:44:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 16:44:58
Data point term sent to Coder	System	29 Oct 2020 16:43:36
User entered 'Flu Vaccine'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Flu Vaccine'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '.5'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered empty.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '21 Sep 2020'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '0'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered '21 Sep 2020'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	29 Oct 2020 16:42:06
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg (b) (4)	17 Sep 2020 22:27:45

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User entered empty.	System	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth	29 Oct 2020 16:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg	(b) (4) 17 Sep 2020 22:27:45
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User entered empty.	System	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth	29 Oct 2020 16:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg	(b) (4) 17 Sep 2020 22:27:45
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:13
User entered empty.	System	29 Oct 2020 16:42:42
DataPoint activated with code reason code Data required.	Matthew Musikanth	29 Oct 2020 16:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Karen Mylerberg	(b) (4) 17 Sep 2020 22:27:45
	(b) (4)	

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 23:09:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 23:09:31
Data point term sent to Coder	System	13 Apr 2021 23:08:48
User entered 'TYLENOL'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'MUSCLE/BODY ACHE AND HEADACHE'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered '500'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered '05 Feb 2021'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered '05 Feb 2021'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User entered '2'	System	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User entered '1'	System	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:53
User entered '804 (804)'	System	13 Apr 2021 23:07:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:27:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:27:50
Data point term sent to Coder	System	13 Apr 2021 23:18:00
Data point term sent to Coder	System	13 Apr 2021 23:09:56
User entered 'TRAMADOL'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered 'POST LAPAROSCOPIC CHOLESCYSTECTOMY PAIN RELIEF' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:17:36
User entered 'ABDOMINAL PAIN SECONDARY TO CHOLELITHIASIS'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered '40'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered '02 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:10:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 23:09:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:36:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
Data point term sent to Coder	System	14 Apr 2021 19:24:26
Query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:23:49
User opened query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:19:50
Data point term sent to Coder	System	13 Apr 2021 23:12:58
User entered 'MOTRIN'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered 'ABDOMINAL PAIN SECONDARY TO CHOLELITHIASIS'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered '400'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered '31 Aug 2020'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered '31 Aug 2020'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User entered empty.	System	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User entered empty.	System	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:00
User entered empty.	System	13 Apr 2021 23:12:41

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: MYLANTA [ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:17:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:17:09
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
Data point term sent to Coder	System	15 Apr 2021 15:52:40
User closed query 'DM-Coding: The trade name MYLANTA can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	System	15 Apr 2021 15:52:18
Query 'DM-Coding: The trade name MYLANTA can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'updated' (Site from System).	Matthew Musikanth (b) (4)	15 Apr 2021 15:52:18
Data point term sent to Coder	System	15 Apr 2021 15:51:39
DataPoint Un-verified.	Matthew Musikanth (b) (4)	15 Apr 2021 15:51:33
User entered 'MYLANTA (Magnesium Hydroxide, Aluminium Hydroxide, Simethicone)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	15 Apr 2021 15:51:33
User opened query 'DM-Coding: The trade name MYLANTA can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	15 Apr 2021 13:32:48

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
Data point term sent to Coder	System	13 Apr 2021 23:14:59
User entered 'MYLANTA'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'ABDOMINA PAIN SECONDARY TO CHOLELITHIASIS'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'TABLE SPOON'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered '31 Aug 2020'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered '31 Aug 2020'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:09:34
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User entered empty.	System	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User entered empty.	System	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:51:06
User entered empty.	System	13 Apr 2021 23:14:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:44:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
Data point term sent to Coder	System	13 Apr 2021 23:17:00
User entered 'ibuprofen'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered 'post laparoscopic cholecystectomy pain relief'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered '400'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered 'three times daily (TID)'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered '02 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:08:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 23:16:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 23:21:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 23:21:40
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 23:21:01
User entered 'MIRALAX'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'post Laparoscopic cholecystectomy'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'table spoon'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered '02 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered '04 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:06:43
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 23:20:03

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 09:00:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 09:00:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
Data point term sent to Coder	System	13 Apr 2021 23:25:07
User entered 'senna'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered 'post laparoscopic cholecystectomy'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered '15'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered '02 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered '04 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:05:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 23:25:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:34:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:34:02
Data point term sent to Coder	System	16 Apr 2021 17:32:30
User entered 'OZEMPIC'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'DIABETES'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0.25 or 0.5'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'every week (QS)'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'UN Jan 2021'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Apr 2021 17:32:13

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:34:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:34:51
Data point term sent to Coder	System	16 Apr 2021 17:34:31
User entered 'AMLODIPINE'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'hypertension'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '5'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '25 Aug 2020'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:33:39

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:37:52
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Apr 2021 17:37:52
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	16 Apr 2021 17:37:33
User entered 'pravastatin'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'diabetes'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '40'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '25 Aug 2020'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:37:30

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:41:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:41:58
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 17:41:39
User entered 'dilaudid'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 17:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 17:41:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 17:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 17:41:34
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0.2 or 0.5'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 17:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 17:41:56
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 17:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 17:41:34
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'q4h prn'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:41:34

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (4)	19 Apr 2021 14:48:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (4)	19 Apr 2021 14:48:40
Data point term sent to Coder	System	16 Apr 2021 17:58:59
User entered 'lidocaine 1%'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0.25'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mL (mL)'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	16 Apr 2021 17:59:59
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	16 Apr 2021 17:59:59
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	16 Apr 2021 17:58:40
User entered 'once (ONCE)'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'intradermal'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 17:59:59
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:58:40

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
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)	16 Apr 2021 18:02:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 18:02:52
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 18:02:03
User entered 'acetaminophen'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:15:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:15:55
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Apr 2021 18:15:55
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:01:20
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '650'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Q4h prn'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:01:20

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:07:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:07:05
Data point term sent to Coder	System	16 Apr 2021 18:04:12
User entered 'narcen'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:16:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:16:25
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Apr 2021 18:16:25
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:03:36
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0.1'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Q2min prn'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:16:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:16:25
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Apr 2021 18:16:25
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:03:36
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:03:36

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
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)	16 Apr 2021 18:06:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 18:06:57
Data point term sent to Coder	System	16 Apr 2021 18:06:14
User entered 'ceftriaxone'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '2'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'g (g)'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 18:05:43

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:52:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 14:52:42
Data point term sent to Coder	System	16 Apr 2021 18:07:15
User entered 'metronidazole'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:17:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:17:19
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Apr 2021 18:17:19
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:06:47
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '500'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Q8h'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:06:47

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:21:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:21:52
Data point term sent to Coder	System	16 Apr 2021 18:09:18
User entered 'colace'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:19:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:19:05
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Apr 2021 18:19:05
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:08:53
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '100'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'twice daily (BID)'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 18:08:53

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PLANTAGO OVATA, PRODUCTSYNONYM: METAMUCIL [PLANTAGO OVATA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:22:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:22:41
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 18:11:21
User entered 'metamucil'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'packet'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 18:10:24

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:21:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:21:22
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 18:12:24
User entered 'lactulose'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:19:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:19:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 18:19:08
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:12:18
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '20'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'g (g)'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'four times daily (QID)'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 18:12:18

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:30:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:30:37
Data point term sent to Coder	System	16 Apr 2021 18:14:27
User entered 'bisacodyl'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '10'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 18:13:56

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 18:15:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 18:15:49
Data point term sent to Coder	System	16 Apr 2021 18:15:27
User entered 'zofran'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:19:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:19:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 18:19:26
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:15:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'cholecystitis'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '4'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Q6H PRN'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:15:00

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:54:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:54:38
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 18:18:30
User entered 'MILK OF MAGNESIA'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'CHOLECYSTITIS'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '30'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'mL (mL)'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '02 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 18:17:38

US3112119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:10:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:37:45
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User closed query 'Per ETRTR: According to SAE page "Cholecystitis secondary to Cholelithiasis", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:02:20
Query 'Per ETRTR: According to SAE page "Cholecystitis secondary to Cholelithiasis", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'updated' (Site from CRA). Signature has been broken.	Brenda Grande (b) (4)	06 Apr 2021 20:35:10
	(b) (4)	
	Brenda Grande (b) (4)	06 Apr 2021 20:33:41
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	06 Apr 2021 20:33:41
	(b) (4)	
User opened query 'Per ETRTR: According to SAE page "Cholecystitis secondary to Cholelithiasis", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:15:27
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:44
User entered 'No (N)'	Brenda Grande (b) (4)	22 Feb 2021 22:32:10
	(b) (4)	

US3112119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:10:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:38:04
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User entered '1 Apr 2021'	Brenda Grande (b) (4)	06 Apr 2021 20:34:38

US3112119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:10:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:40:05
DataPoint Un-verified.	Matthew Musikanth	13 Apr 2021 22:38:57
	(b) (4)	
Signature has been broken.	Matthew Musikanth	13 Apr 2021 22:38:57
	(b) (4)	
User entered 'Laparoscopic CHOLECYSTECTOMY' reason for change: Data Entry Error	Matthew Musikanth	13 Apr 2021 22:38:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:38:04
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User entered 'Cholecystectomy' reason for change: Data Entry Error	Matthew Musikanth	07 Apr 2021 16:08:34
	(b) (4)	
User entered 'Cholecystitis secondary to Cholelithiasis'	Brenda Grande (b) (4)	06 Apr 2021 20:34:38
	(b) (4)	

US3112119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:10:35

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:38:04
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User entered 'Adverse Event (AE)'	Brenda Grande (b) (4)	06 Apr 2021 20:34:38

US3112119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:10:35

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:38:04
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User entered empty.	Brenda Grande (b) (4)	06 Apr 2021 20:34:38

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'USA-US062-2021-MRNA-1273-P301000015'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Todd'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Simmons'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '9040 Friars Road Suite 540'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'San Diego'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'CA'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '92108'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'US'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 14:46:44
User entered '5'	System	19 Apr 2021 14:40:53
User entered '4'	System	14 Apr 2021 13:35:35
User entered '3'	System	12 Apr 2021 20:13:15
User entered '2'	System	07 Apr 2021 20:29:39
User entered '1'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'USA-US062-2021-MRNA-1273-P301000015'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Todd'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Simmons'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '9040 Friars Road Suite 540'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'San Diego'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'CA'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '92108'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'US'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 14:46:44
User entered '5'	System	19 Apr 2021 14:40:53
User entered '4'	System	14 Apr 2021 13:35:35
User entered '3'	System	12 Apr 2021 20:13:15
User entered '2'	System	07 Apr 2021 20:29:39
User entered '1'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User entered '05/Apr/2021 11:48'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:10:35

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)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'USA-US062-2021-MRNA-1273-P301000015'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Todd'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Simmons'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '9040 Friars Road Suite 540'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'San Diego'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'CA'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '92108'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'US'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 14:46:44
User entered '5'	System	19 Apr 2021 14:40:53
User entered '4'	System	14 Apr 2021 13:35:35
User entered '3'	System	12 Apr 2021 20:13:15
User entered '2'	System	07 Apr 2021 20:29:39
User entered '1'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
User entered '07/Apr/2021 16:29'	System	07 Apr 2021 20:29:39

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:10:35

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)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 20:29:39

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'USA-US062-2021-MRNA-1273-P301000015'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Todd'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Simmons'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '9040 Friars Road Suite 540'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'San Diego'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'CA'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '92108'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'US'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 14:46:44
User entered '5'	System	19 Apr 2021 14:40:53
User entered '4'	System	14 Apr 2021 13:35:35
User entered '3'	System	12 Apr 2021 20:13:15
User entered '2'	System	07 Apr 2021 20:29:39
User entered '1'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User entered '12/Apr/2021 16:13'	System	12 Apr 2021 20:13:15

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:10:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:40:56
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 20:13:15

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'USA-US062-2021-MRNA-1273-P301000015'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Todd'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Simmons'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '9040 Friars Road Suite 540'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'San Diego'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'CA'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '92108'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'US'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 14:46:44
User entered '5'	System	19 Apr 2021 14:40:53
User entered '4'	System	14 Apr 2021 13:35:35
User entered '3'	System	12 Apr 2021 20:13:15
User entered '2'	System	07 Apr 2021 20:29:39
User entered '1'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered '14/Apr/2021 09:35'	System	14 Apr 2021 13:35:35

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:10:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:40:56
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:52
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 13:35:35

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'USA-US062-2021-MRNA-1273-P301000015'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Todd'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Simmons'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '9040 Friars Road Suite 540'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'San Diego'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'CA'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '92108'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'US'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 14:46:44
User entered '5'	System	19 Apr 2021 14:40:53
User entered '4'	System	14 Apr 2021 13:35:35
User entered '3'	System	12 Apr 2021 20:13:15
User entered '2'	System	07 Apr 2021 20:29:39
User entered '1'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '19/Apr/2021 10:40'	System	19 Apr 2021 14:40:53

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:10:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:40:56
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 14:40:53

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'USA-US062-2021-MRNA-1273-P301000015'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Yes (Y)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'No (N)'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Todd'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'Simmons'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '9040 Friars Road Suite 540'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'San Diego'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered 'CA'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:48:55
User entered '92108'	System	05 Apr 2021 16:48:09

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:35:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:43
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 20:29:43
User entered 'US'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 14:46:44
User entered '5'	System	19 Apr 2021 14:40:53
User entered '4'	System	14 Apr 2021 13:35:35
User entered '3'	System	12 Apr 2021 20:13:15
User entered '2'	System	07 Apr 2021 20:29:39
User entered '1'	System	05 Apr 2021 16:49:02

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered '21/Apr/2021 10:46'	System	21 Apr 2021 14:46:44

US3112119

Folder: SAE USA-US062-2021-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:10:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:17
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 14:46:44