

US3902051 (Prod: Synexus - Optimal Research - Melbourne)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:18:11

All time stamps listed in this document are displayed in GMT

US3902051

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Participant ID

US3902051

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

US3902051

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3902051

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3902051

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	9 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3902051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3902051

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Were any significant conditions reported?

Yes ☒

No ☐

US3902051

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 17:36:19

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Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3902051

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3902051

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Condition	DIABETES 2
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3902051

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3902051

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Condition	RIGHT KNEE PAIN
Start date (dd MMM yyyy)	UN MAY 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3902051

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3902051

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:58 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 10:58
Height (<i>xxx.x</i>)	74 in
Weight (<i>xxx.x</i>)	285 lb
BMI (<i>xxx.x</i>)	36.66834 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)	

US3902051

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3902051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3902051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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	

US3902051

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 190391

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Height	ND - Not Done
Weight	ND - Not Done

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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)	9 SEP 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 10:58
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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)	9 SEP 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 13:45
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 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)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3902051

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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.

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 12:40 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 12:40

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

What was the frequency of the study treatment dosing? ONCE

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

US3902051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	12:06 (24 HR)
Collection date and time (derived)	9 SEP 2020 12:06

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:08	9 SEP 2020 12:08
Nasopharyngeal Swab 2	No		

US3902051

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

09 SEP 2020 13:12

PC Open Date & Time

09 SEP 2020 13:00

PC Close Date & Time

09 SEP 2020 15:30

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

97.3 °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

10 SEP 2020 07:49

PC Open Date & Time

09 SEP 2020 16:25

PC Close Date & Time

10 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

97.8 °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

11 SEP 2020 07:42

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 07:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

13 SEP 2020 07:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

97.7 °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

14 SEP 2020 07:34

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 07:40

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

97.8 °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

16 SEP 2020 08:13

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

09 SEP 2020 13:12

PC Open Date & Time

09 SEP 2020 13:00

PC Close Date & Time

09 SEP 2020 15:30

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

10 SEP 2020 07:49

PC Open Date & Time

09 SEP 2020 16:25

PC Close Date & Time

10 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

4

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

11 SEP 2020 07:43

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

12 SEP 2020 07:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

13 SEP 2020 07:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

14 SEP 2020 07:34

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

15 SEP 2020 07:40

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

16 SEP 2020 08:14

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 13:13
PC Open Date & Time	09 SEP 2020 13:00
PC Close Date & Time	09 SEP 2020 15:30

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 07:50
PC Open Date & Time	09 SEP 2020 16:25
PC Close Date & Time	10 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

48 of 1943

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 07:44
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 1943

EAB) (1725)

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 07:04
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

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 ☒

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 07:44
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

54 of 1943

EAB) (1725)

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 07:35
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

56 of 1943

EAB) (1725)

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 07:41
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

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)

58 of 1943

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 08:14
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3902051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT2

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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 OCT 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 09:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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)	7 OCT 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:16
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3902051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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.

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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) 07 OCT 2020

What was the treatment time? (00:00-23:59) 10:41 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 10:41

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

US3902051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	10:04 (24 HR)
Collection date and time (derived)	7 OCT 2020 10:04

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Collection date (dd MMM yyyy)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:05	7 OCT 2020 10:05
Nasopharyngeal Swab 2	No		

US3902051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

07 OCT 2020 11:17

PC Open Date & Time

07 OCT 2020 11:01

PC Close Date & Time

07 OCT 2020 13:31

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	07 OCT 2020 17:51
PC Open Date & Time	07 OCT 2020 14:26
PC Close Date & Time	08 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

98.9 °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 OCT 2020 18:29

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °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

09 OCT 2020 15:46

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

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

10 OCT 2020 23:27

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

98.2 °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

11 OCT 2020 13:51

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 13:13

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 13:35

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

07 OCT 2020 11:18

PC Open Date & Time

07 OCT 2020 11:01

PC Close Date & Time

07 OCT 2020 13:31

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

07 OCT 2020 17:52

PC Open Date & Time

07 OCT 2020 14:26

PC Close Date & Time

08 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

5

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

08 OCT 2020 18:29

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

09 OCT 2020 15:46

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

10 OCT 2020 23:27

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

11 OCT 2020 13:51

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

12 OCT 2020 13:13

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

13 OCT 2020 13:35

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 11:18
PC Open Date & Time	07 OCT 2020 11:01
PC Close Date & Time	07 OCT 2020 13:31

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 17:52
PC Open Date & Time	07 OCT 2020 14:26
PC Close Date & Time	08 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 1943

EAB) (1725)

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 18:30
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

96 of 1943

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 15:47
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

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 ☒

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 23:28
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

100 of 1943

EAB) (1725)

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 13:52
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

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 ☒

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

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 ☒

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 13:35
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3902051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	08:36 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 08:36
Temperature (<i>xxx.x</i>)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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.

US3902051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

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

Collection date (dd MMM yyyy)	4 NOV 2020
-------------------------------	------------

Collection time (00:00-23:59)	09:30 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	4 NOV 2020 09:30
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US3902051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:19

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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	09 NOV 2020 07:11:58
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 08:24:27

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 07:58:18
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 08:16:06

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 07:28:06

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 07:39:06
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 00:16:20

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

Patient Cloud Open Date & Time	25 DEC 2020 00:01
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Patient Cloud Close Date & Time	29 DEC 2020 23:59
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US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 00:04:46
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 00:46:31
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

22 JAN 2021 08:19:04

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

29 JAN 2021 04:43:22

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 00:01:50

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

12 FEB 2021 07:43:43

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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	19 FEB 2021 07:40:41
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

26 FEB 2021 00:01:39

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	09 APR 2021 07:44:59
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 08:10:39

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

24 APR 2021 08:41:18

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 11:01:28

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 <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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 <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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 <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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

Patient Cloud Open Date & Time	12 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 <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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 <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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 <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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

Patient Cloud Open Date & Time	19 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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="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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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 ☐

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3902051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:18:11

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		08 APR 2021 09:36:19

US3902051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:41:59

Generated On: 10 Jun 2021 10:18:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3902051

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:41:59

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3902051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

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.

US3902051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3902051

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:11

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"/>

US3902051

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:18:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3902051

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

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

Visit date (dd MMM yyyy)	21 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3902051

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 16:41:59

Generated On: 10 Jun 2021 10:18:11

Date of updated informed consent (dd MMM yyyy) 21 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3902051

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

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

Collection date (dd MMM yyyy)	21 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:12 (24 HR)
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Collection date and time (derived)	21 JAN 2021 13:12
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US3902051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	13:13
Collection Date and Time (derived)	21 JAN 2021 13:13

US3902051

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

AEID

Adverse event

WORSENING OF FREQUENT
URINATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

331 of 1943

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	_____

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

AEID	USA-US210-2021-MRNA-1273-P30 1000004
Adverse event	RESPIRATORY SYNCYTIAL VIRUS
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)	19 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	21 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	333 of 1943

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

SUBJECT CONTACTED SITE ON
29MAR2021 TO REPORT HE HAS
BEEN IN THE HOSPITAL SINCE
21MAR2021 DUE TO HAVING
DIFFICULTY BREATHING THAT
STARTED 19MAR2021. SUBJECT
WAS TESTED FOR COVID-19
AND WAS NEGATIVE, BUT
TESTED POSITIVE FOR RSV.
SUBJECT IS UNSURE WHAT
MEDS HAVE BEEN GIVEN.
MEDICAL RECORDS RELEASE
FORM WILL BE MAILED AND
SUBJECT TO SIGN AND SEND
BACK. SUBJECT WAS HOPING
TO BE DISCHARGED ON
29MAR2021, BUT HAD TO WAIT
TO SEE THE DOCTOR. ONCE
MEDICAL RECORDS ARE
RECEIVED AND REVIEWED PI
TO COMPLETE NARRATIVE FOR
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

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

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

Yes ☒

No ☐

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

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

337 of 1943

EAB) (1725)

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

339 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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 2000	
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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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 2000	
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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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 1995
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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication NIFEDIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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 MAR 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

349 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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 2000
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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication ADVAIR DISKUS FLUTICASON
PROPIONATE/ SALMETEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 250/ 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication BYSTOLIC NEBIVOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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)

353 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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 MAR 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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication COMBIVENT (IPRATROPIUM
BROMIDE/ ALBUTEROL) 90MCG

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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 MAR 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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication IPRATROPIUM BROMIDE

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 0.05

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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)		08 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 AUG 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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication TAMSULOSIN HCL (FLOMAX)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF FREQUENT URINATION

Dose per administration 0.8

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

AT BEDTIME

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 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"/>

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication AE #2: RSV

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

365 of 1943

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 20:43:56

Generated On: 10 Jun 2021 10:18:11

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

US3902051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 17:36:18

Generated On: 10 Jun 2021 10:18:11

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3902051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:18:11

Date of study discontinuation/completion (<i>dd MMM yyyy</i>)	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death (<i>dd MMM yyyy</i>)	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 16:41:59

Generated On: 10 Jun 2021 10:18:11

SAEID	USA-US210-2021-MRNA-1273-P301000004
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	MURRAY
Investigator's Last Name	KIMMEL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 16:41:59

Generated On: 10 Jun 2021 10:18:11

SAEID	USA-US210-2021-MRNA-1273-P301000004
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	MURRAY
Investigator's Last Name	KIMMEL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	31/MAR/2021 13:38
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

US3902051 (Prod: Synexus - Optimal Research - Melbourne)

US3902051

Form: Participant Creation

Generated On: 10 Jun 2021 10:18:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'US3902051'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:51:41

US3902051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:47:02
	(b) (4)	

US3902051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:51:42

US3902051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:47:02
	(b) (4)	

US3902051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'SCRN'	System	09 Sep 2020 16:47:02

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:51:43

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '66'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'YEARS'	System	09 Sep 2020 16:49:20

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '66'	System	09 Sep 2020 16:49:36

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Male (M)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'I'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:20
	(b) (4)	

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '9 Sep 2020'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:36
	(b) (4)	

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'Sep 2020'	System	09 Sep 2020 16:49:36

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '2020'	System	09 Sep 2020 16:49:36

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Amendment 3 (3)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:36
	(b) (4)	

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:36
	(b) (4)	

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:36
	(b) (4)	

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:36
	(b) (4)	

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:36
	(b) (4)	

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:51:42

US3902051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '1'	System	09 Sep 2020 16:49:42

US3902051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:49:42
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:18:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 11:50:20
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:09:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:09:40
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 12:08:21
User entered 'asthma'	Katrina Carlson (b) (4)	22 Sep 2020 12:07:45
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'un UNK 2005'	Katrina Carlson (b) (4)	22 Sep 2020 12:07:45
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:07:45
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:07:45
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:07:45
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:07:45
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'Jan 2005'	System	22 Sep 2020 12:07:45

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '2005'	System	22 Sep 2020 12:07:45

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:07:45

US3902051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:07:45

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:10:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:10:46
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 12:09:21
User entered 'hypertension'	Katrina Carlson (b) (4)	22 Sep 2020 12:09:05
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'un UNK 1995'	Katrina Carlson (b) (4)	22 Sep 2020 12:09:05
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:09:05
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:09:05
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:09:05
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:09:05
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'Jan 1995'	System	22 Sep 2020 12:09:05

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '1995'	System	22 Sep 2020 12:09:05

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:09:05

US3902051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:09:05

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
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 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:12:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:12:46
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 12:12:23
User entered 'diabetes 2'	Katrina Carlson (b) (4)	22 Sep 2020 12:11:22
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'un UNK 2010'	Katrina Carlson (b) (4)	22 Sep 2020 12:11:22
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:11:22
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:11:22
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:11:22
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:11:22
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'Jan 2010'	System	22 Sep 2020 12:11:22

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '2010'	System	22 Sep 2020 12:11:22

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:11:22

US3902051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:11:22

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:12:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:12:47
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 12:12:23
User entered 'hypercholesterolemia'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:03
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'un UNK 2000'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:03
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:03
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:03
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:12:03
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:03
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'Jan 2000'	System	22 Sep 2020 12:12:03

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '2000'	System	22 Sep 2020 12:12:03

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:12:03

US3902051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:12:03

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:14:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:14:38
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 12:13:24
User entered 'right knee pain'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:34
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'un May 2019'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:34
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:34
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:34
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:12:34
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:12:34
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'May 2019'	System	22 Sep 2020 12:12:34

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '2019'	System	22 Sep 2020 12:12:34

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:12:34

US3902051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:12:34

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:15:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 12:15:38
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 12:14:26
User entered 'hypothyroidism'	Katrina Carlson (b) (4)	22 Sep 2020 12:13:37
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'un UNK 2000'	Katrina Carlson (b) (4)	22 Sep 2020 12:13:37
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:13:37
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:13:37
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:13:37
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:13:37
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'Jan 2000'	System	22 Sep 2020 12:13:37

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '2000'	System	22 Sep 2020 12:13:37

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:13:37

US3902051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	22 Sep 2020 12:13:37

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urination frequency of - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 13:36:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 13:36:34
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 13:35:54
User entered 'Frequent Urination'	Taylor Atkinson (b) (4)	14 Oct 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'un Mar 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	14 Oct 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	14 Oct 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'Mar 2020'	System	14 Oct 2020 13:35:32
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '2020'	System	14 Oct 2020 13:35:32
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	14 Oct 2020 13:35:32
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	14 Oct 2020 13:35:32
DataPoint activated with code reason code Data required.	Taylor Atkinson (b) (4)	14 Oct 2020 13:33:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Katrina Carlson (b) (4)	22 Sep 2020 12:17:30
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '09 Sep 2020'	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '10:58'	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '09 Sep 2020 10:58'	System	22 Sep 2020 12:21:44

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '74' in	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	
DataPoint set to visible.	System	09 Sep 2020 16:49:42

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '285' lb	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	
DataPoint set to visible.	System	09 Sep 2020 16:49:42

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '36.66834'	System	22 Sep 2020 12:21:44
DataPoint set to visible.	System	09 Sep 2020 16:49:42

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'kg/m2'	System	22 Sep 2020 12:21:44
DataPoint set to visible.	System	09 Sep 2020 16:49:42

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'bpm'	System	22 Sep 2020 12:21:44

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'breaths/min'	System	22 Sep 2020 12:21:44

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44
	(b) (4)	

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'mmHg'	System	22 Sep 2020 12:21:44

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Katrina Carlson (b) (4)	22 Sep 2020 12:21:44

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'mmHg'	System	22 Sep 2020 12:21:44

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54

US3902051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54

US3902051

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	22 Sep 2020 12:21:58
	(b) (4)	

US3902051

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '09 Sep 2020'	Katrina Carlson (b) (4)	22 Sep 2020 12:21:58
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'I'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Katrina Carlson (b) (4)	22 Sep 2020 12:25:53
	(b) (4)	

US3902051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:38:50

US3902051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '9 Sep 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:38:50

US3902051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	25 Sep 2020 20:38:50

US3902051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'VISIT1'	System	25 Sep 2020 20:38:50

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 15:34:25

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '190391'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 15:34:25

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 15:34:25

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

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)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:42:21

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

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)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:42:21

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:42:21

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:42:21

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:42:21

US3902051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:11

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:42:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:47:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:47:09

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Pre-Dose (PREDOSE)'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '9 Sep 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '10:58'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '9 Sep 2020 10:58'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '98.2' F	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '65'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'bpm'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '16'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'breaths/min'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '135'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '76'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Post-Dose (POSTDOSE)'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '9 Sep 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '13:45'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '9 Sep 2020 13:45'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '97.3' F	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '72'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'bpm'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '16'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'breaths/min'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '138'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '78'	Bram Swarr (b) (4)	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	25 Sep 2020 20:40:41

US3902051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:40:47

US3902051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:40:47

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 09-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:33:22
Query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 09-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	03 Nov 2020 22:58:38
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 22:42:16
User opened query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 09-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:27:54
User entered '9 Sep 2020'	Taylor Atkinson (b) (4)	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '12:40'	Taylor Atkinson (b) (4)	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '09 Sep 2020 12:40'	System	03 Nov 2020 22:42:16
User entered '9 Sep 2020 12:40'	System	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Right Arm (RIGHT ARM)'	Taylor Atkinson (b) (4)	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'ONCE'	System	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 16:50:17

US3902051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:43:03

US3902051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '9 Sep 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:43:03

US3902051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '12:06'	Bram Swarr (b) (4)	25 Sep 2020 20:43:03

US3902051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '9 Sep 2020 12:06'	System	25 Sep 2020 20:43:03

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:18:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '9 Sep 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bram Swarr (b) (4)	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '12:08'	Bram Swarr (b) (4)	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '9 Sep 2020 12:08'	System	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bram Swarr (b) (4)	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered empty.	System	25 Sep 2020 20:43:17

US3902051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:43:33

US3902051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	25 Sep 2020 20:43:33

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:11:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3fd19190-daef-40b5-9597-79452d3cfade'	System	09 Sep 2020 17:12:17
User entered 'Yes (Y)'	System	09 Sep 2020 17:12:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:11:58', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3fd19190-daef-40b5-9597-79452d3cfade'	System	09 Sep 2020 17:12:17
User entered '97.3'	System	09 Sep 2020 17:12:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3fd19190-daef-40b5-9597-79452d3cfade'	System	09 Sep 2020 17:12:17
User entered 'No (N)'	System	09 Sep 2020 17:12:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3fd19190-daef-40b5-9597-79452d3cfade'	System	09 Sep 2020 17:12:17
User entered '09 Sep 2020 13:12'	System	09 Sep 2020 17:12:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 13:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 15:30'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:48:54', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5771c6c7-4d10-4b12-abc6-a8e55820ae03'	System	10 Sep 2020 11:49:24
User entered 'Yes (Y)'	System	10 Sep 2020 11:49:24

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:10', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5771c6c7-4d10-4b12-abc6-a8e55820ae03'	System	10 Sep 2020 11:49:24
User entered '97.3'	System	10 Sep 2020 11:49:24

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:15', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5771c6c7-4d10-4b12-abc6-a8e55820ae03'	System	10 Sep 2020 11:49:24
User entered 'No (N)'	System	10 Sep 2020 11:49:24

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:22', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5771c6c7-4d10-4b12-abc6-a8e55820ae03'	System	10 Sep 2020 11:49:24
User entered '10 Sep 2020 07:49'	System	10 Sep 2020 11:49:24

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 16:25'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 2'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:42:22', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1f051325-3e84-4d06-bb00-9187eb396ebd'	System	11 Sep 2020 11:42:52
User entered 'Yes (Y)'	System	11 Sep 2020 11:42:52

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:42:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1f051325-3e84-4d06-bb00-9187eb396ebd'	System	11 Sep 2020 11:42:52
User entered '97.8'	System	11 Sep 2020 11:42:52

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:42:42', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1f051325-3e84-4d06-bb00-9187eb396ebd'	System	11 Sep 2020 11:42:52
User entered 'No (N)'	System	11 Sep 2020 11:42:52

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:42:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1f051325-3e84-4d06-bb00-9187eb396ebd'	System	11 Sep 2020 11:42:52
User entered '11 Sep 2020 07:42'	System	11 Sep 2020 11:42:52

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 3'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:02:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4acb74cf-5fa1-4d3b-9aa5-1aa8af44b020'	System	12 Sep 2020 11:03:06
User entered 'Yes (Y)'	System	12 Sep 2020 11:03:06

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:02:51', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4acb74cf-5fa1-4d3b-9aa5-1aa8af44b020'	System	12 Sep 2020 11:03:06
User entered '97.5'	System	12 Sep 2020 11:03:06

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:02:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4acb74cf-5fa1-4d3b-9aa5-1aa8af44b020'	System	12 Sep 2020 11:03:06
User entered 'No (N)'	System	12 Sep 2020 11:03:06

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:01', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4acb74cf-5fa1-4d3b-9aa5-1aa8af44b020'	System	12 Sep 2020 11:03:06
User entered '12 Sep 2020 07:03'	System	12 Sep 2020 11:03:06

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 4'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:07', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'eb49fdaf-9381-4634-be58-e243830d4d59'	System	13 Sep 2020 11:43:29
User entered 'Yes (Y)'	System	13 Sep 2020 11:43:29

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:16', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'eb49fdaf-9381-4634-be58-e243830d4d59'	System	13 Sep 2020 11:43:29
User entered '98.2'	System	13 Sep 2020 11:43:29

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'eb49fdaf-9381-4634-be58-e243830d4d59'	System	13 Sep 2020 11:43:29
User entered 'No (N)'	System	13 Sep 2020 11:43:29

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:25', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'eb49fdaf-9381-4634-be58-e243830d4d59'	System	13 Sep 2020 11:43:29
User entered '13 Sep 2020 07:43'	System	13 Sep 2020 11:43:29

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 5'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:33:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c4dbc402-ac01-4fbd-b237-61f1891b40d7'	System	14 Sep 2020 11:34:21
User entered 'Yes (Y)'	System	14 Sep 2020 11:34:21

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:10', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c4dbc402-ac01-4fbd-b237-61f1891b40d7'	System	14 Sep 2020 11:34:21
User entered '97.7'	System	14 Sep 2020 11:34:21

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c4dbc402-ac01-4fbd-b237-61f1891b40d7'	System	14 Sep 2020 11:34:21
User entered 'No (N)'	System	14 Sep 2020 11:34:21

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:18', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c4dbc402-ac01-4fbd-b237-61f1891b40d7'	System	14 Sep 2020 11:34:21
User entered '14 Sep 2020 07:34'	System	14 Sep 2020 11:34:21

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 6'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1e2e6c7b-16c1-4017-97a3-7c6f1fcb01cd'	System	15 Sep 2020 11:40:28
User entered 'Yes (Y)'	System	15 Sep 2020 11:40:28

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:16', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1e2e6c7b-16c1-4017-97a3-7c6f1fcb01cd'	System	15 Sep 2020 11:40:28
User entered '97.7'	System	15 Sep 2020 11:40:28

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1e2e6c7b-16c1-4017-97a3-7c6f1fcb01cd'	System	15 Sep 2020 11:40:28
User entered 'No (N)'	System	15 Sep 2020 11:40:28

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:24', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '1e2e6c7b-16c1-4017-97a3-7c6f1fcb01cd'	System	15 Sep 2020 11:40:28
User entered '15 Sep 2020 07:40'	System	15 Sep 2020 11:40:28

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 7'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:13:35', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9a4a861f-9955-49e1-ba9c-5f45358c4351'	System	16 Sep 2020 12:14:00
User entered 'Yes (Y)'	System	16 Sep 2020 12:14:00

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:13:47', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9a4a861f-9955-49e1-ba9c-5f45358c4351'	System	16 Sep 2020 12:14:00
User entered '97.8'	System	16 Sep 2020 12:14:00

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:13:50', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9a4a861f-9955-49e1-ba9c-5f45358c4351'	System	16 Sep 2020 12:14:00
User entered 'No (N)'	System	16 Sep 2020 12:14:00

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:13:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9a4a861f-9955-49e1-ba9c-5f45358c4351'	System	16 Sep 2020 12:14:00
User entered '16 Sep 2020 08:13'	System	16 Sep 2020 12:14:00

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:24', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '984b3673-beec-4b69-ace1-ba0c0969ff28'	System	09 Sep 2020 17:12:44
User entered 'None (1)'	System	09 Sep 2020 17:12:44

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:28', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '984b3673-beec-4b69-ace1-ba0c0969ff28'	System	09 Sep 2020 17:12:44
User entered 'No (N)'	System	09 Sep 2020 17:12:44

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:32', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '984b3673-beec-4b69-ace1-ba0c0969ff28'	System	09 Sep 2020 17:12:44
User entered 'No (N)'	System	09 Sep 2020 17:12:44

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '984b3673-beec-4b69-ace1-ba0c0969ff28'	System	09 Sep 2020 17:12:44
User entered 'None (1)'	System	09 Sep 2020 17:12:44

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '984b3673-beec-4b69-ace1-ba0c0969ff28'	System	09 Sep 2020 17:12:44
User entered '09 Sep 2020 13:12'	System	09 Sep 2020 17:12:44

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 13:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 15:30'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:31', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '78a2013c-7e35-4e4e-b637-b7c789b53afe'	System	10 Sep 2020 11:50:03
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 11:50:03

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '78a2013c-7e35-4e4e-b637-b7c789b53afe'	System	10 Sep 2020 11:50:03
User entered 'No (N)'	System	10 Sep 2020 11:50:03

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:44', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '78a2013c-7e35-4e4e-b637-b7c789b53afe'	System	10 Sep 2020 11:50:03
User entered 'No (N)'	System	10 Sep 2020 11:50:03

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '78a2013c-7e35-4e4e-b637-b7c789b53afe'	System	10 Sep 2020 11:50:03
User entered 'None (1)'	System	10 Sep 2020 11:50:03

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:49:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '78a2013c-7e35-4e4e-b637-b7c789b53afe'	System	10 Sep 2020 11:50:03
User entered '10 Sep 2020 07:49'	System	10 Sep 2020 11:50:03

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 16:25'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 2'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:01', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '27c712fb-9e0a-4b80-9500-c15cabe404fb'	System	11 Sep 2020 11:43:37
User entered 'None (1)'	System	11 Sep 2020 11:43:37

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:05', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '27c712fb-9e0a-4b80-9500-c15cabe404fb'	System	11 Sep 2020 11:43:37
User entered 'No (N)'	System	11 Sep 2020 11:43:37

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:10', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '27c712fb-9e0a-4b80-9500-c15cabe404fb'	System	11 Sep 2020 11:43:37
User entered 'Yes (Y)'	System	11 Sep 2020 11:43:37

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:23', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '27c712fb-9e0a-4b80-9500-c15cabe404fb'	System	11 Sep 2020 11:43:37
User entered '4'	System	11 Sep 2020 11:43:37

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:27', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '27c712fb-9e0a-4b80-9500-c15cabe404fb'	System	11 Sep 2020 11:43:37
User entered 'None (1)'	System	11 Sep 2020 11:43:37

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:35', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '27c712fb-9e0a-4b80-9500-c15cabe404fb'	System	11 Sep 2020 11:43:37
User entered '11 Sep 2020 07:43'	System	11 Sep 2020 11:43:37

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 3'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9b39966f-48f7-43c9-8ff3-d5fafa1d2222'	System	12 Sep 2020 11:03:48
User entered 'None (1)'	System	12 Sep 2020 11:03:48

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:25', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9b39966f-48f7-43c9-8ff3-d5fafa1d2222'	System	12 Sep 2020 11:03:48
User entered 'No (N)'	System	12 Sep 2020 11:03:48

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9b39966f-48f7-43c9-8ff3-d5fafa1d2222'	System	12 Sep 2020 11:03:48
User entered 'No (N)'	System	12 Sep 2020 11:03:48

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:42', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9b39966f-48f7-43c9-8ff3-d5fafa1d2222'	System	12 Sep 2020 11:03:48
User entered 'None (1)'	System	12 Sep 2020 11:03:48

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:46', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9b39966f-48f7-43c9-8ff3-d5fafa1d2222'	System	12 Sep 2020 11:03:48
User entered '12 Sep 2020 07:03'	System	12 Sep 2020 11:03:48

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 4'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:30', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5caac7eb-386d-4d47-a9ef-63aeb5989028'	System	13 Sep 2020 11:43:49
User entered 'None (1)'	System	13 Sep 2020 11:43:49

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5caac7eb-386d-4d47-a9ef-63aeb5989028'	System	13 Sep 2020 11:43:49
User entered 'No (N)'	System	13 Sep 2020 11:43:49

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:37', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5caac7eb-386d-4d47-a9ef-63aeb5989028'	System	13 Sep 2020 11:43:49
User entered 'No (N)'	System	13 Sep 2020 11:43:49

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5caac7eb-386d-4d47-a9ef-63aeb5989028'	System	13 Sep 2020 11:43:49
User entered 'None (1)'	System	13 Sep 2020 11:43:49

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:46', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5caac7eb-386d-4d47-a9ef-63aeb5989028'	System	13 Sep 2020 11:43:49
User entered '13 Sep 2020 07:43'	System	13 Sep 2020 11:43:49

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 5'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:26', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b4bee58a-d289-4def-b47f-e826532102cc'	System	14 Sep 2020 11:34:42
User entered 'None (1)'	System	14 Sep 2020 11:34:42

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:29', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b4bee58a-d289-4def-b47f-e826532102cc'	System	14 Sep 2020 11:34:42
User entered 'No (N)'	System	14 Sep 2020 11:34:42

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:32', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b4bee58a-d289-4def-b47f-e826532102cc'	System	14 Sep 2020 11:34:42
User entered 'No (N)'	System	14 Sep 2020 11:34:42

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:35', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b4bee58a-d289-4def-b47f-e826532102cc'	System	14 Sep 2020 11:34:42
User entered 'None (1)'	System	14 Sep 2020 11:34:42

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:38', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b4bee58a-d289-4def-b47f-e826532102cc'	System	14 Sep 2020 11:34:42
User entered '14 Sep 2020 07:34'	System	14 Sep 2020 11:34:42

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 6'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:33', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'd5c24175-5ab9-41e2-8c3b-83040e26d28a'	System	15 Sep 2020 11:40:55
User entered 'None (1)'	System	15 Sep 2020 11:40:55

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:37', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'd5c24175-5ab9-41e2-8c3b-83040e26d28a'	System	15 Sep 2020 11:40:55
User entered 'No (N)'	System	15 Sep 2020 11:40:55

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:40', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'd5c24175-5ab9-41e2-8c3b-83040e26d28a'	System	15 Sep 2020 11:40:55
User entered 'No (N)'	System	15 Sep 2020 11:40:55

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:44', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'd5c24175-5ab9-41e2-8c3b-83040e26d28a'	System	15 Sep 2020 11:40:55
User entered 'None (1)'	System	15 Sep 2020 11:40:55

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:50', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'd5c24175-5ab9-41e2-8c3b-83040e26d28a'	System	15 Sep 2020 11:40:55
User entered '15 Sep 2020 07:40'	System	15 Sep 2020 11:40:55

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 7'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:01', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '455ebaa5-efec-425d-bb82-02609a9e698e'	System	16 Sep 2020 12:14:19
User entered 'None (1)'	System	16 Sep 2020 12:14:19

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:05', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '455ebaa5-efec-425d-bb82-02609a9e698e'	System	16 Sep 2020 12:14:19
User entered 'No (N)'	System	16 Sep 2020 12:14:19

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:07', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '455ebaa5-efec-425d-bb82-02609a9e698e'	System	16 Sep 2020 12:14:19
User entered 'No (N)'	System	16 Sep 2020 12:14:19

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:11', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '455ebaa5-efec-425d-bb82-02609a9e698e'	System	16 Sep 2020 12:14:19
User entered 'None (1)'	System	16 Sep 2020 12:14:19

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:15', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '455ebaa5-efec-425d-bb82-02609a9e698e'	System	16 Sep 2020 12:14:19
User entered '16 Sep 2020 08:14'	System	16 Sep 2020 12:14:19

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered 'None (0)'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered 'None (0)'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:56', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered 'None (0)'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:12:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered 'None (0)'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:13:02', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered 'None (0)'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:13:05', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered 'None (0)'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:13:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered 'No (N)'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-09T13:13:18', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '584a9178-b741-4b30-aaab-d75707a88760'	System	09 Sep 2020 17:13:21
User entered '09 Sep 2020 13:13'	System	09 Sep 2020 17:13:21

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 13:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 15:30'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:05', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered 'None (0)'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:11', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered 'None (0)'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered 'None (0)'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:17', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered 'None (0)'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:21', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered 'None (0)'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:23', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered 'None (0)'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:27', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered 'No (N)'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-10T07:50:33', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '088c70e1-0834-42a3-a7c8-f1315debd376'	System	10 Sep 2020 11:50:35
User entered '10 Sep 2020 07:50'	System	10 Sep 2020 11:50:35

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Sep 2020 16:25'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 2'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:42', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered 'None (0)'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:45', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered 'None (0)'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:48', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered 'None (0)'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered 'None (0)'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered 'None (0)'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:43:58', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered 'None (0)'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:44:02', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered 'No (N)'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-11T07:44:07', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b95ddbb6-dac2-4d5e-a9d4-5cb4c29feb0a'	System	11 Sep 2020 11:44:11
User entered '11 Sep 2020 07:44'	System	11 Sep 2020 11:44:11

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 3'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:53', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered 'None (0)'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered 'None (0)'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:03:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered 'None (0)'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:04:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered 'None (0)'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:04:07', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered 'None (0)'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:04:11', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered 'None (0)'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:04:18', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered 'No (N)'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-12T07:04:23', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bcc10f72-3c84-4dad-a935-66810bd4cd12'	System	12 Sep 2020 11:04:25
User entered '12 Sep 2020 07:04'	System	12 Sep 2020 11:04:25

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 4'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered 'None (0)'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:43:56', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered 'None (0)'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:44:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered 'None (0)'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:44:07', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered 'None (0)'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:44:10', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered 'None (0)'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:44:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered 'None (0)'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:44:17', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered 'No (N)'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-13T07:44:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ad05e01f-8594-490e-a82d-718dfe2f14ca'	System	13 Sep 2020 11:44:26
User entered '13 Sep 2020 07:44'	System	13 Sep 2020 11:44:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 5'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:45', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered 'None (0)'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered 'None (0)'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered 'None (0)'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:34:56', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered 'None (0)'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:35:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered 'None (0)'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:35:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered 'None (0)'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:35:07', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered 'No (N)'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-14T07:35:12', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'e3577e47-54ce-4e59-8f06-e770931326a7'	System	14 Sep 2020 11:35:15
User entered '14 Sep 2020 07:35'	System	14 Sep 2020 11:35:15

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 6'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:40:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered 'None (0)'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:41:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered 'None (0)'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:41:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered 'None (0)'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:41:08', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered 'None (0)'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:41:12', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered 'None (0)'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:41:16', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered 'None (0)'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:41:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered 'No (N)'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-15T07:41:24', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9ed008f-2bf5-49d8-b965-b15d9fcaeb2b'	System	15 Sep 2020 11:41:26
User entered '15 Sep 2020 07:41'	System	15 Sep 2020 11:41:26

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 7'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered 'None (0)'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:23', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered 'None (0)'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:26', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered 'None (0)'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:30', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered 'None (0)'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered 'None (0)'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:38', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered 'None (0)'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered 'No (N)'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-09-16T08:14:45', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c965e093-58e5-48c9-a59f-2b4dbcedac0a'	System	16 Sep 2020 12:14:49
User entered '16 Sep 2020 08:14'	System	16 Sep 2020 12:14:49

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:50:17

US3902051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:52:38

US3902051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '16 Sep 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:52:38

US3902051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	25 Sep 2020 20:52:38

US3902051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:52:38

US3902051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:52:46

US3902051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	25 Sep 2020 20:52:46

US3902051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:52:59

US3902051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '23 Sep 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:52:59

US3902051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	25 Sep 2020 20:52:59

US3902051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:52:59

US3902051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:53:03

US3902051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	25 Sep 2020 20:53:03

US3902051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	30 Sep 2020 20:17:37

US3902051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '30 Sep 2020'	Bram Swarr (b) (4)	30 Sep 2020 20:17:37

US3902051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	30 Sep 2020 20:17:37

US3902051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	30 Sep 2020 20:17:37

US3902051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	30 Sep 2020 20:17:51

US3902051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	30 Sep 2020 20:17:51

US3902051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:17:10

US3902051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '7 Oct 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 13:17:10

US3902051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Home (Home)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:17:10

US3902051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'VISIT2'	System	14 Oct 2020 13:17:10

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09
	(b) (4)	

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '7 Oct 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '09:00'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '7 Oct 2020 09:00'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '97.6' F	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Oral (Oral)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '79'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'bpm'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '14'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'breaths/min'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:35:15
Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'As per PI, NCS' (Site from DM).	Taylor Atkinson (b) (4)	04 Nov 2020 13:09:55
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 07:59:04
User entered '153'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:35:20
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'As per PI, NCS' (Site from DM).	Taylor Atkinson (b) (4)	04 Nov 2020 13:09:58
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 07:59:21
User entered '92'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Atkinson (b) (4) (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '7 Oct 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '11:16'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '7 Oct 2020 11:16'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '97.3' F	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Oral (Oral)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '62'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'bpm'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '16'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'breaths/min'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:35:59
Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'As per PI, NCS' (Site from DM).	Taylor Atkinson (b) (4)	04 Nov 2020 13:10:06
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 07:59:43
User entered '143'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '88'	Taylor Atkinson (b) (4)	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	14 Oct 2020 13:21:09

US3902051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:24:02

US3902051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:24:02

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Per CDM: Please complete all forms for this visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:40:01
Query 'Per CDM: Please complete all forms for this visit. Thank you.' answered with 'completed' (Site from DM).	Taylor Atkinson (b) (4)	03 Nov 2020 22:59:31
User opened query 'Per CDM: Please complete all forms for this visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29(Treatment 2 date). Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 07-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:33:11
Query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29(Treatment 2 date). Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 07-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	03 Nov 2020 22:59:45
User entered '07 Oct 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 22:59:36
User opened query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29(Treatment 2 date). Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 07-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:27:17
Query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 09-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:27:01
User opened query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 09-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:26:56
User entered '7 Oct 2020'	Taylor Atkinson (b) (4)	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '10:41'	Taylor Atkinson (b) (4)	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '07 Oct 2020 10:41'	System	03 Nov 2020 22:59:36
User entered '7 Oct 2020 10:41'	System	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Right Arm (RIGHT ARM)'	Taylor Atkinson (b) (4)	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'ONCE'	System	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 14:51:54

US3902051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:18

US3902051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '7 Oct 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:18

US3902051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '10:04'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:18

US3902051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '7 Oct 2020 10:04'	System	14 Oct 2020 13:25:18

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '7 Oct 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '10:05'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '7 Oct 2020 10:05'	System	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered empty.	System	14 Oct 2020 13:25:38

US3902051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:25:44

US3902051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	14 Oct 2020 13:25:44

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:17:35', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '05af7c9e-3fd5-4fb3-936d-f5156324edad'	System	07 Oct 2020 15:17:58
User entered 'Yes (Y)'	System	07 Oct 2020 15:17:58

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:17:47', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '05af7c9e-3fd5-4fb3-936d-f5156324edad'	System	07 Oct 2020 15:17:58
User entered '97.3'	System	07 Oct 2020 15:17:58

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:17:50', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '05af7c9e-3fd5-4fb3-936d-f5156324edad'	System	07 Oct 2020 15:17:58
User entered 'No (N)'	System	07 Oct 2020 15:17:58

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:17:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '05af7c9e-3fd5-4fb3-936d-f5156324edad'	System	07 Oct 2020 15:17:58
User entered '07 Oct 2020 11:17'	System	07 Oct 2020 15:17:58

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 11:01'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 13:31'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:08', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6bb0d2b6-890f-44e5-b95a-ea1625182d84'	System	07 Oct 2020 21:51:32
User entered 'Yes (Y)'	System	07 Oct 2020 21:51:32

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:15', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6bb0d2b6-890f-44e5-b95a-ea1625182d84'	System	07 Oct 2020 21:51:32
User entered '98.6'	System	07 Oct 2020 21:51:32

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:21', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6bb0d2b6-890f-44e5-b95a-ea1625182d84'	System	07 Oct 2020 21:51:32
User entered 'No (N)'	System	07 Oct 2020 21:51:32

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:28', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6bb0d2b6-890f-44e5-b95a-ea1625182d84'	System	07 Oct 2020 21:51:32
User entered '07 Oct 2020 17:51'	System	07 Oct 2020 21:51:32

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 2'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fd8570cc-c5d4-4a11-857e-2727a003ef88'	System	08 Oct 2020 22:29:25
User entered 'Yes (Y)'	System	08 Oct 2020 22:29:25

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:11', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fd8570cc-c5d4-4a11-857e-2727a003ef88'	System	08 Oct 2020 22:29:25
User entered '98.9'	System	08 Oct 2020 22:29:25

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fd8570cc-c5d4-4a11-857e-2727a003ef88'	System	08 Oct 2020 22:29:25
User entered 'No (N)'	System	08 Oct 2020 22:29:25

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:18', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fd8570cc-c5d4-4a11-857e-2727a003ef88'	System	08 Oct 2020 22:29:25
User entered '08 Oct 2020 18:29'	System	08 Oct 2020 22:29:25

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 3'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:45:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fe13f232-1449-4306-adff-8d7dbed69f29'	System	09 Oct 2020 19:46:29
User entered 'Yes (Y)'	System	09 Oct 2020 19:46:29

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:15', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fe13f232-1449-4306-adff-8d7dbed69f29'	System	09 Oct 2020 19:46:29
User entered '99.3'	System	09 Oct 2020 19:46:29

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:18', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fe13f232-1449-4306-adff-8d7dbed69f29'	System	09 Oct 2020 19:46:29
User entered 'No (N)'	System	09 Oct 2020 19:46:29

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:22', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'fe13f232-1449-4306-adff-8d7dbed69f29'	System	09 Oct 2020 19:46:29
User entered '09 Oct 2020 15:46'	System	09 Oct 2020 19:46:29

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 4'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '65e817ce-409f-48d6-92f6-29b20282a908'	System	11 Oct 2020 03:27:26
User entered 'Yes (Y)'	System	11 Oct 2020 03:27:26

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '65e817ce-409f-48d6-92f6-29b20282a908'	System	11 Oct 2020 03:27:26
User entered '97.7'	System	11 Oct 2020 03:27:26

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:16', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '65e817ce-409f-48d6-92f6-29b20282a908'	System	11 Oct 2020 03:27:26
User entered 'No (N)'	System	11 Oct 2020 03:27:26

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '65e817ce-409f-48d6-92f6-29b20282a908'	System	11 Oct 2020 03:27:26
User entered '10 Oct 2020 23:27'	System	11 Oct 2020 03:27:26

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 5'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '110f1b58-5823-47f9-9c84-e2dea59a4f76'	System	11 Oct 2020 17:51:19
User entered 'Yes (Y)'	System	11 Oct 2020 17:51:19

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:10', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '110f1b58-5823-47f9-9c84-e2dea59a4f76'	System	11 Oct 2020 17:51:19
User entered '98.2'	System	11 Oct 2020 17:51:19

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '110f1b58-5823-47f9-9c84-e2dea59a4f76'	System	11 Oct 2020 17:51:19
User entered 'No (N)'	System	11 Oct 2020 17:51:19

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:16', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '110f1b58-5823-47f9-9c84-e2dea59a4f76'	System	11 Oct 2020 17:51:19
User entered '11 Oct 2020 13:51'	System	11 Oct 2020 17:51:19

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 6'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:09', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '91c80dad-fe56-4ed9-8157-4d4ddb9271'	System	12 Oct 2020 17:13:28
User entered 'Yes (Y)'	System	12 Oct 2020 17:13:28

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '91c80dad-fe56-4ed9-8157-4d4ddbdd9271'	System	12 Oct 2020 17:13:28
User entered '98.5'	System	12 Oct 2020 17:13:28

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:23', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '91c80dad-fe56-4ed9-8157-4d4ddbdd9271'	System	12 Oct 2020 17:13:28
User entered 'No (N)'	System	12 Oct 2020 17:13:28

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:26', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '91c80dad-fe56-4ed9-8157-4d4ddbdd9271'	System	12 Oct 2020 17:13:28
User entered '12 Oct 2020 13:13'	System	12 Oct 2020 17:13:28

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 7'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:34:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '80ecaa83-848f-4aba-b22c-2a152f4186fc'	System	13 Oct 2020 17:35:10
User entered 'Yes (Y)'	System	13 Oct 2020 17:35:10

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:34:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '80ecaa83-848f-4aba-b22c-2a152f4186fc'	System	13 Oct 2020 17:35:10
User entered '98.5'	System	13 Oct 2020 17:35:10

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '80ecaa83-848f-4aba-b22c-2a152f4186fc'	System	13 Oct 2020 17:35:10
User entered 'No (N)'	System	13 Oct 2020 17:35:10

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:08', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '80ecaa83-848f-4aba-b22c-2a152f4186fc'	System	13 Oct 2020 17:35:10
User entered '13 Oct 2020 13:35'	System	13 Oct 2020 17:35:10

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:02', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b43455b1-07c8-4ff5-b2c6-08ceccd85afa'	System	07 Oct 2020 15:18:21
User entered 'None (1)'	System	07 Oct 2020 15:18:21

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b43455b1-07c8-4ff5-b2c6-08ceccd85afa'	System	07 Oct 2020 15:18:21
User entered 'No (N)'	System	07 Oct 2020 15:18:21

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:09', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b43455b1-07c8-4ff5-b2c6-08ceccd85afa'	System	07 Oct 2020 15:18:21
User entered 'No (N)'	System	07 Oct 2020 15:18:21

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:12', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b43455b1-07c8-4ff5-b2c6-08ceccd85afa'	System	07 Oct 2020 15:18:21
User entered 'None (1)'	System	07 Oct 2020 15:18:21

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:16', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'b43455b1-07c8-4ff5-b2c6-08ceccd85afa'	System	07 Oct 2020 15:18:21
User entered '07 Oct 2020 11:18'	System	07 Oct 2020 15:18:21

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 11:01'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 13:31'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c183ea1e-2988-4945-a241-075eb0702cd8'	System	07 Oct 2020 21:52:08
User entered 'None (1)'	System	07 Oct 2020 21:52:08

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:44', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c183ea1e-2988-4945-a241-075eb0702cd8'	System	07 Oct 2020 21:52:08
User entered 'No (N)'	System	07 Oct 2020 21:52:08

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:47', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c183ea1e-2988-4945-a241-075eb0702cd8'	System	07 Oct 2020 21:52:08
User entered 'No (N)'	System	07 Oct 2020 21:52:08

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:51:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c183ea1e-2988-4945-a241-075eb0702cd8'	System	07 Oct 2020 21:52:08
User entered 'None (1)'	System	07 Oct 2020 21:52:08

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c183ea1e-2988-4945-a241-075eb0702cd8'	System	07 Oct 2020 21:52:08
User entered '07 Oct 2020 17:52'	System	07 Oct 2020 21:52:08

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 2'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:26', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3d915f0d-69a3-44cd-b3cd-e2f7fb095da0'	System	08 Oct 2020 22:29:51
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 22:29:51

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:29', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3d915f0d-69a3-44cd-b3cd-e2f7fb095da0'	System	08 Oct 2020 22:29:51
User entered 'No (N)'	System	08 Oct 2020 22:29:51

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3d915f0d-69a3-44cd-b3cd-e2f7fb095da0'	System	08 Oct 2020 22:29:51
User entered 'Yes (Y)'	System	08 Oct 2020 22:29:51

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:39', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3d915f0d-69a3-44cd-b3cd-e2f7fb095da0'	System	08 Oct 2020 22:29:51
User entered '5'	System	08 Oct 2020 22:29:51

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:44', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3d915f0d-69a3-44cd-b3cd-e2f7fb095da0'	System	08 Oct 2020 22:29:51
User entered 'None (1)'	System	08 Oct 2020 22:29:51

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:46', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3d915f0d-69a3-44cd-b3cd-e2f7fb095da0'	System	08 Oct 2020 22:29:51
User entered '08 Oct 2020 18:29'	System	08 Oct 2020 22:29:51

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 3'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5aa594cc-a7bd-4073-83b9-242434dbefea'	System	09 Oct 2020 19:46:58
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 19:46:58

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:45', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5aa594cc-a7bd-4073-83b9-242434dbefea'	System	09 Oct 2020 19:46:58
User entered 'No (N)'	System	09 Oct 2020 19:46:58

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5aa594cc-a7bd-4073-83b9-242434dbefea'	System	09 Oct 2020 19:46:58
User entered 'No (N)'	System	09 Oct 2020 19:46:58

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:53', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5aa594cc-a7bd-4073-83b9-242434dbefea'	System	09 Oct 2020 19:46:58
User entered 'None (1)'	System	09 Oct 2020 19:46:58

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:46:56', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5aa594cc-a7bd-4073-83b9-242434dbefea'	System	09 Oct 2020 19:46:58
User entered '09 Oct 2020 15:46'	System	09 Oct 2020 19:46:58

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 4'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:33', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4a9a0705-4972-41bf-b245-64a1d2be66b6'	System	11 Oct 2020 03:27:48
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 03:27:48

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4a9a0705-4972-41bf-b245-64a1d2be66b6'	System	11 Oct 2020 03:27:48
User entered 'No (N)'	System	11 Oct 2020 03:27:48

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:38', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4a9a0705-4972-41bf-b245-64a1d2be66b6'	System	11 Oct 2020 03:27:48
User entered 'No (N)'	System	11 Oct 2020 03:27:48

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:42', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4a9a0705-4972-41bf-b245-64a1d2be66b6'	System	11 Oct 2020 03:27:48
User entered 'None (1)'	System	11 Oct 2020 03:27:48

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:45', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '4a9a0705-4972-41bf-b245-64a1d2be66b6'	System	11 Oct 2020 03:27:48
User entered '10 Oct 2020 23:27'	System	11 Oct 2020 03:27:48

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 5'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:25', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '314a569d-1d85-4d59-8b22-3bbf5863c03a'	System	11 Oct 2020 17:51:39
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 17:51:39

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:27', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '314a569d-1d85-4d59-8b22-3bbf5863c03a'	System	11 Oct 2020 17:51:39
User entered 'No (N)'	System	11 Oct 2020 17:51:39

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:31', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '314a569d-1d85-4d59-8b22-3bbf5863c03a'	System	11 Oct 2020 17:51:39
User entered 'No (N)'	System	11 Oct 2020 17:51:39

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '314a569d-1d85-4d59-8b22-3bbf5863c03a'	System	11 Oct 2020 17:51:39
User entered 'None (1)'	System	11 Oct 2020 17:51:39

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:37', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '314a569d-1d85-4d59-8b22-3bbf5863c03a'	System	11 Oct 2020 17:51:39
User entered '11 Oct 2020 13:51'	System	11 Oct 2020 17:51:39

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 6'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:31', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '77d8b433-0a4c-46c6-a65c-12107a6786ae'	System	12 Oct 2020 17:13:45
User entered 'None (1)'	System	12 Oct 2020 17:13:45

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '77d8b433-0a4c-46c6-a65c-12107a6786ae'	System	12 Oct 2020 17:13:45
User entered 'No (N)'	System	12 Oct 2020 17:13:45

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '77d8b433-0a4c-46c6-a65c-12107a6786ae'	System	12 Oct 2020 17:13:45
User entered 'No (N)'	System	12 Oct 2020 17:13:45

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:40', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '77d8b433-0a4c-46c6-a65c-12107a6786ae'	System	12 Oct 2020 17:13:45
User entered 'None (1)'	System	12 Oct 2020 17:13:45

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:42', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '77d8b433-0a4c-46c6-a65c-12107a6786ae'	System	12 Oct 2020 17:13:45
User entered '12 Oct 2020 13:13'	System	12 Oct 2020 17:13:45

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 7'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0a56c053-134b-4fb4-bf09-d51c5ebec35b'	System	13 Oct 2020 17:35:32
User entered 'None (1)'	System	13 Oct 2020 17:35:32

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:17', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0a56c053-134b-4fb4-bf09-d51c5ebec35b'	System	13 Oct 2020 17:35:32
User entered 'No (N)'	System	13 Oct 2020 17:35:32

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:19', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0a56c053-134b-4fb4-bf09-d51c5ebec35b'	System	13 Oct 2020 17:35:32
User entered 'No (N)'	System	13 Oct 2020 17:35:32

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:22', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0a56c053-134b-4fb4-bf09-d51c5ebec35b'	System	13 Oct 2020 17:35:32
User entered 'None (1)'	System	13 Oct 2020 17:35:32

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:26', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0a56c053-134b-4fb4-bf09-d51c5ebec35b'	System	13 Oct 2020 17:35:32
User entered '13 Oct 2020 13:35'	System	13 Oct 2020 17:35:32

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:22', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered 'None (0)'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:25', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered 'None (0)'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:28', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered 'None (0)'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:31', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered 'None (0)'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered 'None (0)'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered 'None (0)'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:44', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered 'No (N)'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T11:18:48', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6829e202-eba5-4438-98e3-4f2e4803869c'	System	07 Oct 2020 15:18:53
User entered '07 Oct 2020 11:18'	System	07 Oct 2020 15:18:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 11:01'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 13:31'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:11', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered 'No interference with activity (1)'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered 'None (0)'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:18', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered 'None (0)'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:21', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered 'None (0)'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:28', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:32', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered 'None (0)'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered 'No (N)'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-07T17:52:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '860da79a-a66d-487c-a704-90c5b485b5f0'	System	07 Oct 2020 21:52:47
User entered '07 Oct 2020 17:52'	System	07 Oct 2020 21:52:47

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 2'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered 'None (0)'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:54', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered 'None (0)'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:57', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered 'None (0)'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:29:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered 'None (0)'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:30:02', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered 'None (0)'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:30:05', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered 'None (0)'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:30:09', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered 'No (N)'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-08T18:30:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '46bcd148-b796-4d0f-8d5d-947fef027718'	System	08 Oct 2020 22:30:18
User entered '08 Oct 2020 18:30'	System	08 Oct 2020 22:30:18

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 3'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered 'No interference with activity (1)'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered 'None (0)'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:09', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered 'None (0)'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:11', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered 'None (0)'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered 'None (0)'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:17', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered 'None (0)'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:19', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered 'No (N)'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-09T15:47:23', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9f505e7d-7495-47f0-a7e0-9d1dc8d560e0'	System	09 Oct 2020 19:47:26
User entered '09 Oct 2020 15:47'	System	09 Oct 2020 19:47:26

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 4'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered 'None (0)'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered 'None (0)'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:54', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered 'None (0)'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:27:57', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered 'None (0)'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:28:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered 'None (0)'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:28:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered 'None (0)'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:28:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered 'No (N)'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-10T23:28:10', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '099338c5-5548-4041-957d-495090b066f9'	System	11 Oct 2020 03:28:15
User entered '10 Oct 2020 23:28'	System	11 Oct 2020 03:28:15

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 5'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:47', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered 'None (0)'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:50', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered 'None (0)'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:53', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered 'None (0)'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered 'None (0)'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:57', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered 'None (0)'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:51:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered 'None (0)'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:52:02', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered 'No (N)'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-11T13:52:05', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '97479c8e-1e18-4327-969b-a3ca91d82f20'	System	11 Oct 2020 17:52:09
User entered '11 Oct 2020 13:52'	System	11 Oct 2020 17:52:09

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 6'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:48', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered 'None (0)'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:51', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered 'None (0)'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:53', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered 'None (0)'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:13:56', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered 'None (0)'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:14:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:14:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered 'None (0)'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:14:09', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered 'No (N)'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-12T13:14:17', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'a48c534b-d42c-42b0-8d7e-9271bda1a204'	System	12 Oct 2020 17:14:20
User entered '12 Oct 2020 13:14'	System	12 Oct 2020 17:14:20

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	07 Oct 2020 14:51:54
User entered 'Day 7'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:33', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered 'None (0)'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:35', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered 'None (0)'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:37', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered 'None (0)'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:39', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered 'None (0)'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered 'None (0)'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:44', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered 'None (0)'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:46', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered 'No (N)'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-10-13T13:35:49', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f519e075-807d-46c6-bf49-5e4d5574cd87'	System	13 Oct 2020 17:35:53
User entered '13 Oct 2020 13:35'	System	13 Oct 2020 17:35:53

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 14:51:54

US3902051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 14:51:54

US3902051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 17:16:59

US3902051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '16 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 17:16:59

US3902051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 17:16:59

US3902051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 17:16:59

US3902051

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 17:17:07

US3902051

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	20 Oct 2020 17:17:07

US3902051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:49:43

US3902051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '21 Oct 2020'	Bram Swarr (b) (4)	05 Nov 2020 21:49:43

US3902051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	05 Nov 2020 21:49:43

US3902051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	05 Nov 2020 21:49:43

US3902051

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:49:54

US3902051

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	05 Nov 2020 21:49:54

US3902051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:50:11

US3902051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '30 Oct 2020'	Bram Swarr (b) (4)	05 Nov 2020 21:50:11

US3902051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	05 Nov 2020 21:50:11

US3902051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	05 Nov 2020 21:50:11

US3902051

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:50:18

US3902051

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	05 Nov 2020 21:50:18

US3902051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:51:52

US3902051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '4 Nov 2020'	Bram Swarr (b) (4)	05 Nov 2020 21:51:52

US3902051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	05 Nov 2020 21:51:52

US3902051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'VISIT3'	System	05 Nov 2020 21:51:52

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '4 Nov 2020'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '08:36'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '4 Nov 2020 08:36'	System	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '96.9' F	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '73'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'bpm'	System	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '14'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'breaths/min'	System	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '124'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '70'	Bram Swarr (b) (4)	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'mmHg'	System	05 Nov 2020 21:52:37

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30

US3902051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30

US3902051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Bram Swarr (b) (4)	05 Nov 2020 21:53:07

US3902051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	05 Nov 2020 21:53:07

US3902051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:53:30

US3902051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '4 Nov 2020'	Bram Swarr (b) (4)	05 Nov 2020 21:53:30

US3902051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '09:30'	Bram Swarr (b) (4)	05 Nov 2020 21:53:30

US3902051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered '4 Nov 2020 09:30'	System	05 Nov 2020 21:53:30

US3902051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Nov 2020 21:54:02

US3902051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	05 Nov 2020 21:54:02

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 64'	System	09 Sep 2020 16:50:17

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-09T07:11:45', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0b9405fb-0e24-4450-b12b-516842907a75'	System	09 Nov 2020 12:12:03
User entered 'No (N)'	System	09 Nov 2020 12:12:03

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-09T07:11:52', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0b9405fb-0e24-4450-b12b-516842907a75'	System	09 Nov 2020 12:12:03
User entered 'No (N)'	System	09 Nov 2020 12:12:03

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-09T07:11:58', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0b9405fb-0e24-4450-b12b-516842907a75'	System	09 Nov 2020 12:12:03
User entered '09 Nov 2020 07:11:58'	System	09 Nov 2020 12:12:03

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 16:50:17

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered 'Day 71'	System	09 Sep 2020 16:50:17

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-16T08:24:13', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5af44abd-a627-4c45-a182-e2590850eb3d'	System	16 Nov 2020 13:24:32
User entered 'No (N)'	System	16 Nov 2020 13:24:32

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-16T08:24:21', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5af44abd-a627-4c45-a182-e2590850eb3d'	System	16 Nov 2020 13:24:32
User entered 'No (N)'	System	16 Nov 2020 13:24:32

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-16T08:24:27', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '5af44abd-a627-4c45-a182-e2590850eb3d' User entered '16 Nov 2020 08:24:27'	System	16 Nov 2020 13:24:32
	System	16 Nov 2020 13:24:32

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 16:50:17

US3902051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:16:53
Data entry locked.	System	09 Sep 2020 16:50:17
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 16:50:17

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2020-11-23T07:58:07', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c2b41c36-76b2-4329-8b5b-ae8482a092f0'	System	23 Nov 2020 12:58:21
User entered 'No (N)'	System	23 Nov 2020 12:58:21

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2020-11-23T07:58:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c2b41c36-76b2-4329-8b5b-ae8482a092f0'	System	23 Nov 2020 12:58:21
User entered 'No (N)'	System	23 Nov 2020 12:58:21

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-23T07:58:18', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'c2b41c36-76b2-4329-8b5b-ae8482a092f0'	System	23 Nov 2020 12:58:21
User entered '23 Nov 2020 07:58:18'	System	23 Nov 2020 12:58:21

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2020-11-27T08:15:57', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'cf07bd7d-6b54-4b26-a964-495ae57c7e5a'	System	27 Nov 2020 13:16:10
User entered 'No (N)'	System	27 Nov 2020 13:16:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2020-11-27T08:16:01', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'cf07bd7d-6b54-4b26-a964-495ae57c7e5a'	System	27 Nov 2020 13:16:10
User entered 'No (N)'	System	27 Nov 2020 13:16:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-11-27T08:16:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'cf07bd7d-6b54-4b26-a964-495ae57c7e5a'	System	27 Nov 2020 13:16:10
User entered '27 Nov 2020 08:16:06'	System	27 Nov 2020 13:16:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2020-12-04T07:27:59', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '40a9dc21-8803-4bd8-bcb5-21e68c56fb5d'	System	04 Dec 2020 12:28:11
User entered 'No (N)'	System	04 Dec 2020 12:28:11

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2020-12-04T07:28:02', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '40a9dc21-8803-4bd8-bcb5-21e68c56fb5d'	System	04 Dec 2020 12:28:11
User entered 'No (N)'	System	04 Dec 2020 12:28:11

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-12-04T07:28:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '40a9dc21-8803-4bd8-bcb5-21e68c56fb5d'	System	04 Dec 2020 12:28:11
User entered '04 Dec 2020 07:28:06'	System	04 Dec 2020 12:28:11

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2020-12-11T07:38:55', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '000cd2ff-0d44-4d24-b287-3fac0a4f339e'	System	11 Dec 2020 12:39:10
User entered 'No (N)'	System	11 Dec 2020 12:39:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2020-12-11T07:39:03', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '000cd2ff-0d44-4d24-b287-3fac0a4f339e'	System	11 Dec 2020 12:39:10
User entered 'No (N)'	System	11 Dec 2020 12:39:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-12-11T07:39:06', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '000cd2ff-0d44-4d24-b287-3fac0a4f339e'	System	11 Dec 2020 12:39:10
User entered '11 Dec 2020 07:39:06'	System	11 Dec 2020 12:39:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2020-12-18T00:15:38', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '009f3dfd-4a0b-45a8-8c44-f0d73d102cb8'	System	18 Dec 2020 05:16:25
User entered 'No (N)'	System	18 Dec 2020 05:16:25

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2020-12-18T00:16:14', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '009f3dfd-4a0b-45a8-8c44-f0d73d102cb8'	System	18 Dec 2020 05:16:25
User entered 'No (N)'	System	18 Dec 2020 05:16:25

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2020-12-18T00:16:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '009f3dfd-4a0b-45a8-8c44-f0d73d102cb8'	System	18 Dec 2020 05:16:25
User entered '18 Dec 2020 00:16:20'	System	18 Dec 2020 05:16:25

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-01-08T00:04:34', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0c99b654-0177-4623-9d17-9b3c0ae2b89b'	System	08 Jan 2021 05:04:50
User entered 'No (N)'	System	08 Jan 2021 05:04:50

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-01-08T00:04:40', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0c99b654-0177-4623-9d17-9b3c0ae2b89b'	System	08 Jan 2021 05:04:50
User entered 'No (N)'	System	08 Jan 2021 05:04:50

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-01-08T00:04:46', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0c99b654-0177-4623-9d17-9b3c0ae2b89b'	System	08 Jan 2021 05:04:50
User entered '08 Jan 2021 00:04:46'	System	08 Jan 2021 05:04:50

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-01-15T00:46:20', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0ee54e5b-a327-4844-b757-e3703df596bc'	System	15 Jan 2021 05:46:35
User entered 'No (N)'	System	15 Jan 2021 05:46:35

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-01-15T00:46:24', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0ee54e5b-a327-4844-b757-e3703df596bc'	System	15 Jan 2021 05:46:35
User entered 'No (N)'	System	15 Jan 2021 05:46:35

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-01-15T00:46:31', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '0ee54e5b-a327-4844-b757-e3703df596bc'	System	15 Jan 2021 05:46:35
User entered '15 Jan 2021 00:46:31'	System	15 Jan 2021 05:46:35

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-01-22T08:18:53', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3270b612-eb59-453a-8514-dc9aa616417b'	System	22 Jan 2021 13:19:07
User entered 'No (N)'	System	22 Jan 2021 13:19:07

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-01-22T08:18:58', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3270b612-eb59-453a-8514-dc9aa616417b'	System	22 Jan 2021 13:19:07
User entered 'No (N)'	System	22 Jan 2021 13:19:07

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-01-22T08:19:04', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '3270b612-eb59-453a-8514-dc9aa616417b'	System	22 Jan 2021 13:19:07
User entered '22 Jan 2021 08:19:04'	System	22 Jan 2021 13:19:07

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-01-29T04:43:12', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '894d9130-59ea-451e-a145-c4d01284087f'	System	29 Jan 2021 09:43:26
User entered 'No (N)'	System	29 Jan 2021 09:43:26

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-01-29T04:43:17', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '894d9130-59ea-451e-a145-c4d01284087f'	System	29 Jan 2021 09:43:26
User entered 'No (N)'	System	29 Jan 2021 09:43:26

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-01-29T04:43:22', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '894d9130-59ea-451e-a145-c4d01284087f' User entered '29 Jan 2021 04:43:22'	System	29 Jan 2021 09:43:26

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-02-05T00:01:43', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '987fa15c-49f8-4cec-9cfc-9da7f74da5c4'	System	05 Feb 2021 05:02:24
User entered 'No (N)'	System	05 Feb 2021 05:02:24

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-02-05T00:01:46', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '987fa15c-49f8-4cec-9cfc-9da7f74da5c4'	System	05 Feb 2021 05:02:24
User entered 'No (N)'	System	05 Feb 2021 05:02:24

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-02-05T00:01:50', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '987fa15c-49f8-4cec-9cfc-9da7f74da5c4'	System	05 Feb 2021 05:02:24
User entered '05 Feb 2021 00:01:50'	System	05 Feb 2021 05:02:24

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-02-12T07:43:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '70e3a33f-541b-47e3-8818-78c38fe6b279'	System	12 Feb 2021 12:43:49
User entered 'No (N)'	System	12 Feb 2021 12:43:49

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-02-12T07:43:39', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '70e3a33f-541b-47e3-8818-78c38fe6b279'	System	12 Feb 2021 12:43:49
User entered 'No (N)'	System	12 Feb 2021 12:43:49

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-02-12T07:43:43', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '70e3a33f-541b-47e3-8818-78c38fe6b279'	System	12 Feb 2021 12:43:49
User entered '12 Feb 2021 07:43:43'	System	12 Feb 2021 12:43:49

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-02-19T07:40:33', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '364bcd9c-7e30-48c9-91b7-518cfb15c435'	System	19 Feb 2021 12:40:44
User entered 'No (N)'	System	19 Feb 2021 12:40:44

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-02-19T07:40:36', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '364bcd9c-7e30-48c9-91b7-518cfb15c435'	System	19 Feb 2021 12:40:44
User entered 'No (N)'	System	19 Feb 2021 12:40:44

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-02-19T07:40:41', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '364bcd9c-7e30-48c9-91b7-518cfb15c435'	System	19 Feb 2021 12:40:44
User entered '19 Feb 2021 07:40:41'	System	19 Feb 2021 12:40:44

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-02-26T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bb91c4af-5efe-4f2a-9324-a7f5cc88cbde' User entered 'No (N)'	System	26 Feb 2021 05:02:44

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-02-26T00:01:31-05:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bb91c4af-5efe-4f2a-9324-a7f5cc88cbde'	System	26 Feb 2021 05:02:44
User entered 'No (N)'	System	26 Feb 2021 05:02:44

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-02-26T00:01:39-05:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'bb91c4af-5efe-4f2a-9324-a7f5cc88cbde'	System	26 Feb 2021 05:02:44
User entered '26 Feb 2021 00:01:39'	System	26 Feb 2021 05:02:44

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-04-09T07:44:29-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9c060d8e-0e43-414a-be94-a5307fc36970'	System	09 Apr 2021 11:45:10
User entered 'Yes (Y)'	System	09 Apr 2021 11:45:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-04-09T07:44:36-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9c060d8e-0e43-414a-be94-a5307fc36970'	System	09 Apr 2021 11:45:10
User entered 'No (N)'	System	09 Apr 2021 11:45:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-04-09T07:44:44-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9c060d8e-0e43-414a-be94-a5307fc36970'	System	09 Apr 2021 11:45:10
User entered 'No (N)'	System	09 Apr 2021 11:45:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-04-09T07:44:49-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9c060d8e-0e43-414a-be94-a5307fc36970'	System	09 Apr 2021 11:45:10
User entered 'Yes (Y)'	System	09 Apr 2021 11:45:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Please 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 (02f267a3f05c5d3e)', Time: '2021-04-09T07:44:55-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9c060d8e-0e43-414a-be94-a5307fc36970'	System	09 Apr 2021 11:45:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Apr 2021 11:45:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-04-09T07:44:59-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '9c060d8e-0e43-414a-be94-a5307fc36970'	System	09 Apr 2021 11:45:10
User entered '09 Apr 2021 07:44:59'	System	09 Apr 2021 11:45:10

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-04-18T08:10:32-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '93bedadf-bd0b-45b0-9125-795565d6d9a2'	System	18 Apr 2021 12:10:43
User entered 'No (N)'	System	18 Apr 2021 12:10:43

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-04-18T08:10:35-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '93bedadf-bd0b-45b0-9125-795565d6d9a2'	System	18 Apr 2021 12:10:43
User entered 'No (N)'	System	18 Apr 2021 12:10:43

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-04-18T08:10:39-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '93bedadf-bd0b-45b0-9125-795565d6d9a2'	System	18 Apr 2021 12:10:43
User entered '18 Apr 2021 08:10:39'	System	18 Apr 2021 12:10:43

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-04-24T08:41:12-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6f6ca89f-727e-4fee-9c22-3e0d052d161e' User entered 'No (N)'	System	24 Apr 2021 12:41:20
	System	24 Apr 2021 12:41:20

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-04-24T08:41:15-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6f6ca89f-727e-4fee-9c22-3e0d052d161e'	System	24 Apr 2021 12:41:20
User entered 'No (N)'	System	24 Apr 2021 12:41:20

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-04-24T08:41:18-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: '6f6ca89f-727e-4fee-9c22-3e0d052d161e'	System	24 Apr 2021 12:41:20
User entered '24 Apr 2021 08:41:18'	System	24 Apr 2021 12:41:20

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[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 (02f267a3f05c5d3e)', Time: '2021-05-02T11:01:17-05:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ca76a59e-04c2-43e2-8b15-8cd4da0ebfb3'	System	02 May 2021 16:03:45
User entered 'No (N)'	System	02 May 2021 16:03:45

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

Have you been exposed to someone with 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 (02f267a3f05c5d3e)', Time: '2021-05-02T11:01:21-05:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ca76a59e-04c2-43e2-8b15-8cd4da0ebfb3'	System	02 May 2021 16:03:45
User entered 'No (N)'	System	02 May 2021 16:03:45

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-05-02T11:01:28-05:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'ca76a59e-04c2-43e2-8b15-8cd4da0ebfb3'	System	02 May 2021 16:03:45
User entered '02 May 2021 11:01:28'	System	02 May 2021 16:03:45

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:32:42

US3902051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:42
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:32:42

US3902051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:18:11

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)	30 Apr 2021 22:51:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-04-08T09:36:13-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9a16594-a8e4-4c6c-97ec-f3f5fd0f789e'	System	08 Apr 2021 13:36:22
User entered 'No (N)'	System	08 Apr 2021 13:36:22

US3902051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:18:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:51:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02f267a3f05c5d3e)', Time: '2021-04-08T09:36:19-04:00', User OID: 'PatientReportedOutcome (US3902051)', ODM File OID: 'f9a16594-a8e4-4c6c-97ec-f3f5fd0f789e'	System	08 Apr 2021 13:36:22
User entered '08 Apr 2021 09:36:19'	System	08 Apr 2021 13:36:22

US3902051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	09 Dec 2020 14:48:21

US3902051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '2 Dec 2020'	Bram Swarr (b) (4)	09 Dec 2020 14:48:21

US3902051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	09 Dec 2020 14:48:21

US3902051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	09 Dec 2020 14:48:21

US3902051

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	09 Dec 2020 14:48:28

US3902051

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:50:30
User entered 'I'	System	09 Dec 2020 14:48:28

US3902051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:53:13
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Jan 2021 19:38:28

US3902051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:53:13
User entered '5 Jan 2021'	Bram Swarr (b) (4)	05 Jan 2021 19:38:28

US3902051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:53:13
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	05 Jan 2021 19:38:28

US3902051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:53:13
User entered empty.	Bram Swarr (b) (4)	05 Jan 2021 19:38:28

US3902051

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:53:24
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Jan 2021 19:38:33

US3902051

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User entered 'I'	System	05 Jan 2021 19:38:33

US3902051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Feb 2021 19:10:49

US3902051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '4 Feb 2021'	Bram Swarr (b) (4)	05 Feb 2021 19:10:49

US3902051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	05 Feb 2021 19:10:49

US3902051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Bram Swarr (b) (4)	05 Feb 2021 19:10:49

US3902051

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Feb 2021 19:10:55

US3902051

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:38
User entered 'I'	System	05 Feb 2021 19:10:55

US3902051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:34
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Mar 2021 16:42:14

US3902051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:34
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered '8 Mar 2021'	Taylor Atkinson (b) (4)	29 Mar 2021 16:42:14

US3902051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:34
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	29 Mar 2021 16:42:14

US3902051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:34
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered empty.	Taylor Atkinson (b) (4)	29 Mar 2021 16:42:14

US3902051

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:34
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Mar 2021 16:42:22

US3902051

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:34
User entered 'I'	System	29 Mar 2021 16:42:22

US3902051

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:09
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:05:33
	(b) (4)	

US3902051

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:09
User entered '21 Jan 2021'	Taylor Atkinson (b) (4)	03 Feb 2021 13:05:33
	(b) (4)	

US3902051

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:09
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:05:33

US3902051

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 13:05:33

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:17
User entered '21 Jan 2021'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:12

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:56:04

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:17
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:12
	(b) (4)	

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
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 18:56:04

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:17
User entered '21 Jan 2021'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:12

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:17
User entered 'mRNA-1273 (mRNA-1273)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:12

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:17
User entered 'mRNA-1273 (mRNA-1273)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:12

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:17
User entered 'mRNA-1273 (mRNA-1273)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:12

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:17
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	03 Feb 2021 13:06:19
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	03 Feb 2021 13:06:19
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:19
	(b) (4)	
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	03 Feb 2021 13:06:12
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:12
	(b) (4)	

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	03 Feb 2021 13:06:12

US3902051

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered empty.	System	03 Feb 2021 13:06:12

US3902051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:26
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:44
	(b) (4)	

US3902051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:26
User entered '21 Jan 2021'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:44

US3902051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:26
User entered '13:12'	Taylor Atkinson (b) (4)	03 Feb 2021 13:06:44

US3902051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '21 Jan 2021 13:12'	System	03 Feb 2021 13:06:44

US3902051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:36
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Feb 2021 13:07:07
	(b) (4)	

US3902051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:36
User entered '21 Jan 2021'	Taylor Atkinson (b) (4)	03 Feb 2021 13:07:07

US3902051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:54:36
User entered '13:13'	Taylor Atkinson (b) (4)	03 Feb 2021 13:07:07

US3902051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:54
User entered '21 Jan 2021 13:13'	System	03 Feb 2021 13:07:07

US3902051

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:18:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:37
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:51:57
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	01 Mar 2021 14:09:08

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User closed query 'per source AE is worsening of frequent urination' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 15:07:16
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 12:42:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 12:42:59
User signature succeeded.	Murray Kimmel (b) (4) (b) (4)	05 Mar 2021 17:36:20
Data point term sent to Coder	System	02 Mar 2021 14:44:16
Query 'per source AE is worsening of frequent urination' answered with 'Transcription error' (Site from CRA).	Taylor Atkinson (b) (4) (b) (4)	02 Mar 2021 14:43:33
User entered 'WORSENING OF Frequent Urination' reason for change: Data Entry Error	Taylor Atkinson (b) (4) (b) (4)	02 Mar 2021 14:43:24
User opened query 'per source AE is worsening of frequent urination' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 20:53:06
Data point term sent to Coder	System	01 Mar 2021 17:24:36
User entered 'Worsening of Fluid Retention'	Taylor Atkinson (b) (4) (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '15 Sep 2020'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User entered empty.	System	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '18 Nov 2020'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User entered empty.	System	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:29:57
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' answered with 'As per PI, the grading should stay as mild' (Site from DM).	Taylor Atkinson (b) (4) (b) (4)	22 Mar 2021 21:46:27
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:09:59
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Taylor Atkinson (b) (4) (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:24:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 17:24:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:24:01
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:24:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 17:24:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:24:01
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:24:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 17:24:17
User entered 'None (NONE)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:24:01
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'I'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered '0'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered empty.	Taylor Atkinson (b) (4)	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User entered '0'	System	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09
User entered '1'	System	01 Mar 2021 17:24:01

US3902051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:09

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:35
User entered 'USA-US210-2021-mRNA-1273-P301000004'	System	31 Mar 2021 13:38:30
User entered 'New'	(b) (4), (b) (6)	31 Mar 2021 13:38:30

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Respiratory syncytial viral infections, PT: Respiratory syncytial virus infection, LLT: Respiratory syncytial virus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 21:10:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 21:10:05
Data point term sent to Coder	System	30 Mar 2021 21:09:10
User entered 'respiratory syncytial virus'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Mar 2021'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
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)	08 Apr 2021 15:40:43
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Mar 2021 21:11:04
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Mar 2021 21:10:31
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:40:51
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)	31 Mar 2021 10:10:04
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 'to be updated once subject is discharged' (Site from System).	Katrina Carlson (b) (4)	30 Mar 2021 21:11:48
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Mar 2021 21:11:04
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	30 Mar 2021 21:11:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Mar 2021 21:11:04
User entered '1' reason for change: Data Entry Error	Katrina Carlson (b) (4)	30 Mar 2021 21:11:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Mar 2021 21:10:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Mar 2021 21:10:31

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	30 Mar 2021 21:10:31
User entered '0' reason for change: Data Entry Error	Katrina Carlson (b) (4)	30 Mar 2021 21:10:31
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).	(b) (4) System	30 Mar 2021 21:09:10
User entered '1'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Mar 2021'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:40:34
User entered empty.	Katrina Carlson (b) (4)	30 Mar 2021 21:09:10
	(b) (4)	

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 21:11:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 21:11:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Katrina Carlson (b) (4)	30 Mar 2021 21:11:04
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 21:09:10
User entered empty.	Katrina Carlson (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for SAE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 09:31:25
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for SAE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'Pending medical records. This will be updated with any con meds from records. However, subject has not reported any new medications at this time' (Site from DM).	Taylor Atkinson (b) (4)	09 Apr 2021 20:37:38
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for SAE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:49:29
User entered 'I'	Katrina Carlson (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:40:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Katrina Carlson (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:40:22
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)	08 Apr 2021 15:40:06
User entered 'subject contacted site on 29Mar2021 to report he has been in the hospital since 21Mar2021 due to having difficulty breathing that started 19Mar2021. Subject was tested for COVID-19 and was negative, but tested positive for RSV. Subject is unsure what meds have been given. Medical records release form will be mailed and subject to sign and send back. Subject was hoping to be discharged on 29Mar2021, but had to wait to see the doctor. Once medical records are received and reviewed PI to complete narrative for follow up.'	Katrina Carlson (b) (4) (b) (4)	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 21:09:10

US3902051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 21:09:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:18:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:37
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:43:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
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)	26 Sep 2020 06:46:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 06:46:47
Data point term sent to Coder	System	25 Sep 2020 20:44:46
User entered 'tramadol'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'right knee pain'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '50'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'as needed (PRN)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un May 2019'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:44:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:47:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:47:01
	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 20:45:47
User entered 'aspirin'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'heart health'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '81'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4) [REDACTED]	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'once daily (QD)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4) [REDACTED]	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 2000'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:44:56

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:47:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:47:01
	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 20:45:50
User entered 'levothyroxine'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'hypothyroidism'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '200'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User closed query 'Per CDM: Please note that "ug" which means "microgram" is an available option in Dose Unit field. Please consider selecting "ug" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "MCG", if applicable and please remove "MCG" in "If dose unit is Other, specify field". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:34:10
Query 'Per CDM: Please note that "ug" which means "microgram" is an available option in Dose Unit field. Please consider selecting "ug" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "MCG", if applicable and please remove "MCG" in "If dose unit is Other, specify field". Please review and update accordingly. Thank you. ' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	05 Nov 2020 21:48:14
User entered 'ug (ug)' reason for change: Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:48:04
User opened query 'Per CDM: Please note that "ug" which means "microgram" is an available option in Dose Unit field. Please consider selecting "ug" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "MCG", if applicable and please remove "MCG" in "If dose unit is Other, specify field". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:20:18
User entered 'Other (OTHER)'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:48:04
User entered 'mcg'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'once daily (QD)'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 2000'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:45:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:47:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:47:50
Data point term sent to Coder	System	25 Sep 2020 20:46:51
User entered 'lisinopril'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'hypertension'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '20'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'twice daily (BID)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 1995'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:46:03

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
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)	09 Dec 2020 14:53:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 14:53:53
	(b) (4)	
Data point term sent to Coder	System	09 Dec 2020 14:52:48
Coding entries removed.	Bram Swarr (b) (4)	09 Dec 2020 14:52:07
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)	25 Sep 2020 20:47:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:47:51
	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 20:46:55
User entered 'metformin'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'DIABETES type II' reason for change:	Bram Swarr (b) (4)	09 Dec 2020 14:52:07
Data Entry Error		
User entered 'diabetes'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '500'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'twice daily (BID)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 2010'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:46:26

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
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: NIFEDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:48:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:48:53
Data point term sent to Coder User entered 'nifedipine'	System Bram Swarr (b) (4)	25 Sep 2020 20:47:56 25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'hypertension'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '60'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'once daily (QD)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un Mar 2019'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:47:05

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
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) (b) (4)	25 Sep 2020 20:48:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:48:52
Data point term sent to Coder	System	25 Sep 2020 20:47:59
User entered 'pravastatin'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'hypercholesterolemia'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '20'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4) [REDACTED]	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'once daily (QD)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4) [REDACTED]	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 2000'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4) [REDACTED]	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:47:39

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:46:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:46:56
Data point term sent to Coder	System	25 Sep 2020 20:49:00
User entered 'advair diskus fluticason propionate/salmeterol'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'asthma'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '250/ 50'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User closed query 'Per CDM: Please note that "ug" which means "microgram" is an available option in Dose Unit field. Please consider selecting "ug" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "MCG", if applicable and please remove "MCG" in "If dose unit is Other, specify field". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:34:46
Query 'Per CDM: Please note that "ug" which means "microgram" is an available option in Dose Unit field. Please consider selecting "ug" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "MCG", if applicable and please remove "MCG" in "If dose unit is Other, specify field". Please review and update accordingly. Thank you. ' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	05 Nov 2020 21:48:42
User entered 'ug (ug)' reason for change: Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:48:32
User opened query 'Per CDM: Please note that "ug" which means "microgram" is an available option in Dose Unit field. Please consider selecting "ug" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "MCG", if applicable and please remove "MCG" in "If dose unit is Other, specify field". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:20:48
User entered 'Other (OTHER)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:48:32
User entered 'mcg'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'twice daily (BID)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 2005'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:48:20

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 05:16:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 05:16:42
Data point term sent to Coder	System	25 Sep 2020 20:49:01
User entered 'bystolic nebivolol'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'hypertension'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '10'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4) [REDACTED]	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'once daily (QD)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un Mar 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4) [REDACTED]	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:48:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:38:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:38:13
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
Data point term sent to Coder	System	01 Mar 2021 13:47:14
Coding entries removed.	Taylor Atkinson (b) (4)	01 Mar 2021 13:47:03
	(b) (4)	
User closed query 'Per DM CLR: Please update the Medication Name field to include the drug formulation/drug component and specify the # of puffs in the unit field for combination medications. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:42:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: ADRENERGICS AND OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 22:03:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 22:03:41
Data point term sent to Coder	System	18 Dec 2020 21:15:27

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

Name of Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the Medication Name field to include the drug formulation/drug component and specify the # of puffs in the unit field for combination medications. ' answered with 'updated per query' (Site from DM). Coding entries removed.	Bram Swarr (b) (4)	18 Dec 2020 21:14:47
	Bram Swarr (b) (4)	18 Dec 2020 21:14:41
User entered 'COMBIVENT (IPRATROPIUM BROMIDE/ ALBUTEROL) 90mcg' reason for change: Data Entry Error	Bram Swarr (b) (4)	18 Dec 2020 21:14:41
User opened query 'Per DM CLR: Please update the Medication Name field to include the drug formulation/drug component and specify the # of puffs in the unit field for combination medications. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:40:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: ADRENERGICS AND OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 05:24:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 05:24:46
Data point term sent to Coder	System	25 Sep 2020 20:50:04
User entered 'combivent (ipratropium bromide/ albuterol)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'asthma'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '2'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'puff (PUFF)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'as needed (PRN)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:44:30
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	Taylor Atkinson (b) (4)	01 Mar 2021 13:47:09
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4)	01 Mar 2021 13:47:03
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:03:33
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 2005'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:49:31

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:50:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:50:57
Data point term sent to Coder	System	25 Sep 2020 20:50:04
User entered 'furosemide'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'hypertension'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '40'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'once daily (QD)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un Mar 2020'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:49:55

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:51:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:51:59
	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 20:51:08
User entered 'ipratropium bromide'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'asthma'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0.05'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'four times daily (QID)'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Nasal (NASAL)'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'un UNK 2005'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Bram Swarr (b) (4)	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:50:54

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
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)	28 Sep 2020 12:49:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:49:35
Data point term sent to Coder	System	28 Sep 2020 12:48:23
User entered 'Influenza Vaccine'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Influenza'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'I'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User closed query 'Per CDM: Please note that "IU" which means "International Units" is an available option in Dose Unit field. Please consider selecting "IU" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "UNITS", if applicable.Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:35:32
Query 'Per CDM: Please note that "IU" which means "International Units" is an available option in Dose Unit field. Please consider selecting "IU" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "UNITS", if applicable.Thank you. ' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	05 Nov 2020 21:46:58
User entered 'IU (IU)' reason for change: Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:46:50
User opened query 'Per CDM: Please note that "IU" which means "International Units" is an available option in Dose Unit field. Please consider selecting "IU" from the drop-downlist provided for Dose Unit, instead of selecting "Other" and "UNITS", if applicable.Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:59:50
User entered 'Other (OTHER)'	Taylor Atkinson (b) (4) (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:46:50
User entered 'unit'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'once (ONCE)'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User closed query 'Per CDM: Date format is not correctly recorded in Start date & End date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 02-FEB-2019). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:35:51
Query 'Per CDM: Date format is not correctly recorded in Start date & End date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 02-FEB-2019). Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	05 Nov 2020 21:47:23
User entered '08 Aug 2020' reason for change: Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:47:16
User opened query 'Per CDM: Date format is not correctly recorded in Start date & End date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 02-FEB-2019). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:00:28
User entered '8 Aug 2020'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '08 Aug 2020' reason for change: Data Entry Error	Bram Swarr (b) (4)	05 Nov 2020 21:47:30
User entered '8 Aug 2020'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Taylor Atkinson (b) (4)	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User entered empty.	System	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User entered empty.	System	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:42
User entered empty.	System	28 Sep 2020 12:48:10

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:09:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:09:37
User closed query 'Per DM CLR: RE-QUERY: Per response 'Transcription error - corrected'. However, still indication has not been changed. Please consider updating indication to match corresponding AE. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:32:38
Query 'Per DM CLR: RE-QUERY: Per response 'Transcription error - corrected'. However, still indication has not been changed. Please consider updating indication to match corresponding AE. Thank you. ' answered with 'updated to reflect AE' (Site from DM).	Bram Swarr (b) (4)	18 Mar 2021 15:34:28
Data point term sent to Coder	System	18 Mar 2021 15:34:20
Coding entries removed.	Bram Swarr (b) (4)	18 Mar 2021 15:34:18
User opened query 'Per DM CLR: RE-QUERY: Per response 'Transcription error - corrected'. However, still indication has not been changed. Please consider updating indication to match corresponding AE. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 08:27:28
User closed query 'Per DM CLR: Re-Query: Response noted. However, indication is not matching corresponding AE. Please consider changing the indication accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 08:27:28

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Re-Query: Response noted. However, indication is not matching corresponding AE. Please consider changing the indication accordingly. Thank you.' answered with 'Transcription error - corrected' (Site from DM).	Taylor Atkinson (b) (4)	02 Mar 2021 14:46:04
User opened query 'Per DM CLR: Re-Query: Response noted. However, indication is not matching corresponding AE. Please consider changing the indication accordingly. Thank you.' (Site from DM).	(b) (4)	
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition of FREQUENT URINATION worsened. If yes, please review if an AE of "Worsening of Frequent Urination" should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	02 Mar 2021 05:47:35
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 05:47:35
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition of FREQUENT URINATION worsened. If yes, please review if an AE of "Worsening of Frequent Urination" should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	02 Mar 2021 05:47:35
' answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition of FREQUENT URINATION worsened. If yes, please review if an AE of "Worsening of Frequent Urination" should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
' (Site from DM).		
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition of FREQUENT URINATION worsened. If yes, please review if an AE of "Worsening of Frequent Urination" should be recorded, and update con med indication or provide clarification.	Taylor Atkinson (b) (4)	01 Mar 2021 17:28:29
' answered with 'updated' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition of FREQUENT URINATION worsened. If yes, please review if an AE of "Worsening of Frequent Urination" should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	01 Mar 2021 17:28:29
' (Site from DM).		
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition of FREQUENT URINATION worsened. If yes, please review if an AE of "Worsening of Frequent Urination" should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	02 Feb 2021 06:04:06
' (Site from DM).		

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:52:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:52:30
Data point term sent to Coder	System	14 Oct 2020 13:31:50
User entered 'Tamsulosin HCL (Flomax)'	Taylor Atkinson (b) (4) (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Un-verified.	Bram Swarr (b) (4)	18 Mar 2021 15:34:18
User entered 'worsening of FREQUENT URINATION' reason for change: Data Entry Error	Bram Swarr (b) (4)	18 Mar 2021 15:34:18
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Frequent Urination'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0.8'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User closed query 'Per CDM: Please consider selecting "once daily" from the drop-down list in Frequency, instead of selecting "Other" and "BED TIME", if applicable and please remove "BEDTIME " from "If frequency is Other, specify" field. Please review and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:36:14
Query 'Per CDM: Please consider selecting "once daily" from the drop-down list in Frequency, instead of selecting "Other" and "BED TIME", if applicable and please remove "BEDTIME " from "If frequency is Other, specify" field. Please review and update accordingly or provide clarification. Thank you.' answered with 'medication is not taken daily. it is taken at bedtime.' (Site from DM).	Bram Swarr (b) (4)	05 Nov 2020 21:46:29
User opened query 'Per CDM: Please consider selecting "once daily" from the drop-down list in Frequency, instead of selecting "Other" and "BED TIME", if applicable and please remove "BEDTIME " from "If frequency is Other, specify" field. Please review and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:01:13
User entered 'other (OTHER)'	Taylor Atkinson (b) (4) (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'At bedtime'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '15 Sep 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '0'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)' reason for change: Data Entry Error	Bram Swarr (b) (4)	09 Dec 2020 14:49:21
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered '18 Nov 2020' reason for change: Data Entry Error	Bram Swarr (b) (4)	09 Dec 2020 14:49:21
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:53:40
User entered 'No (N)'	Taylor Atkinson (b) (4)	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User entered empty.	System	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User entered empty.	System	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:45
User entered empty.	System	14 Oct 2020 13:31:23

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:43:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:38:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:38:55
Data point term sent to Coder	System	13 Apr 2021 14:26:45
User entered 'prednisone'	Bram Swarr (b) (4)	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered 'AE #2: RSV'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered '4'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered 'mg (mg)'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered empty.	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered 'once daily (QD)'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered empty.	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered 'Oral (ORAL)'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered empty.	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered '29 Mar 2021'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered '0'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	16 Apr 2021 20:43:56
User entered empty.	Bram Swarr (b) (4) [REDACTED]	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:43:56
User entered 'No (N)'	Bram Swarr (b) (4)	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 14:26:34

US3902051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:18:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:20
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Mar 2021 13:59:35
	(b) (4)	

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'USA-US210-2021-MRNA-1273-P301000004'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Yes (Y)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Yes (Y)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Murray'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Kimmel'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered 'US'	System	31 Mar 2021 13:39:00

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 13:39:00

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'USA-US210-2021-MRNA-1273-P301000004'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Yes (Y)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Yes (Y)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'No (N)'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Murray'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:38:52
User entered 'Kimmel'	System	31 Mar 2021 13:38:30

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered 'US'	System	31 Mar 2021 13:39:00

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 13:39:00

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:18:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered '31/Mar/2021 13:38'	System	31 Mar 2021 13:39:00

US3902051

Folder: SAE USA-US210-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:18:11

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.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:00
User entered 'I'	(b) (4), (b) (6)	31 Mar 2021 13:39:00