

US3022052 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:41:23

All time stamps listed in this document are displayed in GMT

US3022052

Form: Participant Creation

Generated On: 26 Nov 2020 08:41:23

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:41:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:41:23

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

Condition	CHRONIC STREP THROAT
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" 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)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
BMI (<i>xxx.x</i>)	
BMI units	
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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

GOVERNMENT DESK WORK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	LIVES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 142129

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:23

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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)	28 JUL 2020
Time of assessment (00:00-23:59)	14:02 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 14:02
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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)	28 JUL 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 15:50
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	28 JUL 2020
What was the treatment time? (00:00-23:59)	15:14 (24 HR)
Treatment Date and Time (derived)	28 JUL 2020 15:14
Which arm was used to give treatment?	Left Arm <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	28 JUL 2020
Collection time (<i>00:00-23:59</i>)	14:47 (24 HR)
Collection date and time (derived)	28 JUL 2020 14:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:41:23

Collection date (<i>dd MMM yyyy</i>)			28 JUL 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:40	28 JUL 2020 14:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 JUL 2020 15:48

PC Open Date & Time

28 JUL 2020 15:34

PC Close Date & Time

28 JUL 2020 18:04

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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 97.2 °F

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

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

PC Time Stamp	28 JUL 2020 20:14
PC Open Date & Time	28 JUL 2020 18:59
PC Close Date & Time	29 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 18:21

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

96.6 °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

30 JUL 2020 12:01

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

98.5 °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

31 JUL 2020 17:24

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

97.9 °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

02 AUG 2020 00:00

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 13:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

04 AUG 2020 06:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 15:50

PC Open Date & Time

28 JUL 2020 15:34

PC Close Date & Time

28 JUL 2020 18:04

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

28 JUL 2020 20:14

PC Open Date & Time

28 JUL 2020 18:59

PC Close Date & Time

29 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 18:20

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 12:00

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

31 JUL 2020 17:23

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 23:59

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

02 AUG 2020 13:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

04 AUG 2020 06:55

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 15:49
PC Open Date & Time	28 JUL 2020 15:34
PC Close Date & Time	28 JUL 2020 18:04

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 20:15
PC Open Date & Time	28 JUL 2020 18:59
PC Close Date & Time	29 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 18:20
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

		Yes <input type="checkbox"/>
PC Time stamp	31 JUL 2020 17:23	
PC Open Date & Time	31 JUL 2020 12:00	
PC Close Date & Time	01 AUG 2020 11:59	

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 23:59
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

		Yes <input type="checkbox"/>
PC Time stamp	02 AUG 2020 13:14	
PC Open Date & Time	02 AUG 2020 12:00	
PC Close Date & Time	03 AUG 2020 11:59	

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 06:55
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3022052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

07 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:58
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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)	11 SEP 2020
Time of assessment (00:00-23:59)	17:16 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:16
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3022052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	11 SEP 2020
What was the treatment time? (00:00-23:59)	16:46 (24 HR)
Treatment Date and Time (derived)	11 SEP 2020 16:46
Which arm was used to give treatment?	Left Arm <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3022052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:08 (24 HR)
Collection date and time (derived)	11 SEP 2020 16:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:41:23

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:21	11 SEP 2020 16:21
Nasopharyngeal Swab 2	No		

US3022052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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 17:15

PC Open Date & Time

11 SEP 2020 17:06

PC Close Date & Time

11 SEP 2020 19:36

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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 98.7 °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	12 SEP 2020 09:38
PC Open Date & Time	11 SEP 2020 20:31
PC Close Date & Time	12 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

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

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

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

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 22:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 13:31

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:14

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

11 SEP 2020 17:15

PC Open Date & Time

11 SEP 2020 17:06

PC Close Date & Time

11 SEP 2020 19:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

12 SEP 2020 09:38

PC Open Date & Time

11 SEP 2020 20:31

PC Close Date & Time

12 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

13 SEP 2020 12:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

14 SEP 2020 12:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

15 SEP 2020 22:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

16 SEP 2020 13:31

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

17 SEP 2020 12:14

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:10
PC Open Date & Time	11 SEP 2020 17:06
PC Close Date & Time	11 SEP 2020 19:36

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 09:39
PC Open Date & Time	11 SEP 2020 20:31
PC Close Date & Time	12 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 13:31
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:14
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3022052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 10:15
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3022052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	09 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:32 (24 HR)
Collection date and time (derived)	09 OCT 2020 10:32

US3022052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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	27 SEP 2020 08:42:56
Patient Cloud Open Date & Time	27 SEP 2020 00:01
Patient Cloud Close Date & Time	01 OCT 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

04 OCT 2020 07:22:34

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 OCT 2020 18:00:24
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 NOV 2020 18:07:59
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 12:07:56

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 12:45:14

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	28 SEP 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	05 OCT 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 138

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

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

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

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

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

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

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 159

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 187

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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°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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 <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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 467

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

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

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

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

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

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

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 <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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

Patient Cloud Open Date & Time	23 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
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Patient Cloud Close Date & Time	28 MAR 2022 23:59
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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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="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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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 ☐

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3022052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022052

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022052

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:41:23

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"/>

US3022052

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:41:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022052

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:41:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

AEID	USA-US051-2020-MRNA-1273-P30 1000010
Adverse event	ESOPHAGEAL CANCER
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)	15 OCT 2020
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	False
Hospital Admission Date (dd MMM yyyy)	
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	

v6.020 DTW (1102) 341 of 1794

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

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

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

SUBJECT REPORTED ON DAY 85
SAFETY PHONE CALL THAT HE
WAS DIAGNOSED WITH
ESOPHAGEAL CANCER AND
HAS AN UPCOMING SURGERY.
CALLED AND FOLLOWED WITH
PATIENT. HE REPORTS OVER
THE PAST 3 YEARS HE HAS
HAD DIFFICULTY IN
SWALLOWING. HE STATES HE
PREVIOUSLY NEVER SOUGHT
CARE FOR THIS TREATED SELF
FOR WHAT HE THOUGHT WAS
ACID REFLUX. SUBJECT
REPORTS HE HAD AN
ENDOSCOPE ON 15OCT2020
AND HAD AN ESOPHAGEAL
TISSUE BIOPSIED. HE
RECEIVED THE RESULTS OF
ESOPHAGEAL CANCER AND
HAS SURGERY SCHEDULED
FOR 09NOV2020 FOR AN
ESOPHAGECTOMY AND
GASTROSTOMY TUBE PLACED
FOR FEEDING. HE DENIES
CHEMO OR RADIATION
PLANNED AT THIS TIME.

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

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:41:23

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

Yes ☒

No ☐

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

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 2 DIABETES
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	JUNUVIA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 2 DIABETES
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

	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 2014	
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"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	LISINOPRIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

	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 2017	
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"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	ROSUVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2013
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	LEVOTHYROXIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

	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 2014
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"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN AT INJECTION SITE
Dose per administration	200
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		26 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	PNEUMOCOCCAL VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	LANSOPRAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ESOPHAGEAL CANCER
Dose per administration	30
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

Name of Medication	REGLIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ESOPHAGEAL CANCER
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

v6.020 DTW (1102)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:41:23

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:41:23

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
09 NOV 2020	ESOPHAGEAL TISSUE BIOPSY	Adverse Event	
09 NOV 2020	GASTROSTOMY TUBE	Adverse Event	

US3022052

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:41:23

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3022052

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:41:23

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:41:23

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/NOV/2020 16:49
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:41:23

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:03
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:41:23

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 16:14
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

US3022052 (Prod: Meridian Clinical Research)

US3022052

Form: Participant Creation

Generated On: 26 Nov 2020 08:41:23

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3022052'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 17:59:10

US3022052

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:32

US3022052

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '28 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 17:59:11

US3022052

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:32

US3022052

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Jul 2020 19:42:32

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 17:59:11

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Age](#)

Audit	User	Time (GMT)
User entered '55'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '55'	System	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[White](#)

Audit	User	Time (GMT)
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:23

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:42:47

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:16

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 17:59:11

US3022052

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:41:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:41:23

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:41:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:56:32

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:42:43
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' answered with 'updated In con med log' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:14:56
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:22:19
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 20:58:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 20:58:59
Data point term sent to Coder	System	28 Jul 2020 20:57:21
User entered 'Diabetes Mellitus Type II'	Morgan Deal (b) (4)	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '2014'	System	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:42:52
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' answered with 'updated in con med log' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:15:05
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:22:44
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 20:58:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 20:58:59
Data point term sent to Coder	System	28 Jul 2020 20:57:21
User entered 'Hypertension'	Morgan Deal (b) (4)	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '2017'	System	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 20:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 20:59:00
Data point term sent to Coder	System	28 Jul 2020 20:58:22
User entered 'Hyperlipidemia'	Morgan Deal (b) (4)	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '2013'	System	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:43:00
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' answered with 'updated in con med log ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:15:15
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:23:00
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 21:01:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 21:01:02
Data point term sent to Coder	System	28 Jul 2020 20:59:22
User entered 'Hypothyroidism'	Morgan Deal (b) (4)	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '2014'	System	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 21:01:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 21:01:02
Data point term sent to Coder	System	28 Jul 2020 20:59:23
User entered 'Tonsillectomy'	Morgan Deal (b) (4)	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 1977'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 20:59:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 20:59:19
User entered 'No (N)' reason for change: Data Entry Error	Morgan Deal (b) (4)	28 Jul 2020 20:59:19
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 20:59:14
User entered empty.	Morgan Deal (b) (4)	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 1977'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 1977'	System	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '1977'	System	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 1977'	System	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '1977'	System	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 12:47:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 12:47:45
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 21:47:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 21:47:58
Data point term sent to Coder	System	28 Jul 2020 21:00:24
User entered 'Chronic Strep Throat'	Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 1977'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 20:59:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 20:59:50
User entered 'No (N)' reason for change: Data Entry Error	Morgan Deal (b) (4)	28 Jul 2020 20:59:50
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 20:59:47
User entered empty.	Morgan Deal (b) (4)	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'un UNK 1977'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 1977'	System	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '1977'	System	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Jan 1977'	System	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '1977'	System	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered 'Yes (Y)'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '28 Jul 2020'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '14:02'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 17:27:05
User entered '28 Jul 2020 14:02'	System	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Height (xxx.x)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '170' cm	(b) (4)	
	Morgan Deal (b) (4)	28 Jul 2020 21:00:34
DataPoint set to visible.	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '83.3' kg	(b) (4)	
	Morgan Deal (b) (4)	28 Jul 2020 21:00:34
DataPoint set to visible.	(b) (4)	
	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

BMI (xxx.x)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 17:27:05
User entered '28.8'	System	28 Jul 2020 21:00:34
DataPoint set to visible.	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[BMI units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'kg/m2'	System	28 Jul 2020 21:00:34
DataPoint set to visible.	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: requery : please note as screening and dosing is done on same date the above mentioned fields should be "ND" as per CCGs. Kindly update ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 04:17:22
Query 'Per CDM: requery : please note as screening and dosing is done on same date the above mentioned fields should be "ND" as per CCGs. Kindly update ' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	26 Aug 2020 17:27:15
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User opened query 'Per CDM: requery : please note as screening and dosing is done on same date the above mentioned fields should be "ND" as per CCGs. Kindly update ' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 08:19:23
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 08:19:23
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	24 Aug 2020 16:24:51
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Aug 2020 21:07:03
User entered '36.8' C	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered 'Oral (Oral)'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '63'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'bpm'	System	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '15'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'breaths/min'	System	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '122'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'mmHg'	System	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '72'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'mmHg'	System	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4)	28 Jul 2020 21:00:42

US3022052

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:00:42

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 16:24:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 16:24:12
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	24 Aug 2020 16:24:12
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 21:01:53
User entered empty.	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

[Specify](#)

Audit	User	Time (GMT)
User entered 'Government desk work'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '0'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:23

[Specify](#)

Audit	User	Time (GMT)
User entered 'Lives in community with ongoing person to person transmissin'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:01:53

US3022052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:02:46

US3022052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:02:46

US3022052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Morgan Deal (b) (4)	28 Jul 2020 21:02:46

US3022052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Jul 2020 21:02:46

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '28 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	28 Jul 2020 18:54:24

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:08:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:08:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 18:54:24
User entered '142129' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 18:54:24

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 18:54:24

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User closed query 'Complete page to confirm that the subject was assigned to the correct cohort.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 13:35:41
Query 'Complete page to confirm that the subject was assigned to the correct cohort.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	22 Aug 2020 01:27:56
User entered 'No (N)'	(b) (4)	
	Shanice Bennett (b) (4)	22 Aug 2020 01:27:32
User opened query 'Complete page to confirm that the subject was assigned to the correct cohort.' (Site from CRA).	(b) (4), (b) (6)	03 Aug 2020 23:59:40

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:27:32

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:27:32

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:27:32

US3022052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:23

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:27:32

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:23

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:32:03
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 16:04:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:04:43
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:46:02
User entered '170' cm	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:04:43
User entered '83.3' kg	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:23

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:32:03
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 16:04:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:04:43
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:46:02
User entered '170' cm	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:04:43
User entered '83.3' kg	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '14:02'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 14:02'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Pulse (xxx)

Audit	User	Time (GMT)
User entered '63'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '15'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:23

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:32:03
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 16:04:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:04:43
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:46:02
User entered '170' cm	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:04:43
User entered '83.3' kg	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '15:50'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 15:50'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Pulse (xxx)

Audit	User	Time (GMT)
User entered '80'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '15'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4)	28 Jul 2020 21:02:56

US3022052

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:02:56

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete the Vital Signs Dosing form' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 04:15:51
Query 'Per CDM: Please complete the Vital Signs Dosing form' answered with 'up[dated]' (Site from DM).	Shanice Bennett (b) (4)	24 Aug 2020 16:27:02
User opened query 'Per CDM: Please complete the Vital Signs Dosing form' (Site from DM).	(b) (4), (b) (6)	23 Aug 2020 21:06:21
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:14'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 15:14'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Shanice Bennett (b) (4) (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:03:18

US3022052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JUL2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 27JUL2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:54:53
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JUL2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 27JUL2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with '28JUL2020 is the correct date' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 13:13:58
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JUL2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 27JUL2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:39:30
User entered '28 Jul 2020'	Morgan Deal (b) (4)	28 Jul 2020 21:03:18

US3022052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:47'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:03:18

US3022052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 14:47'	System	28 Jul 2020 21:03:18

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:41:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however date is recorded as 28JUL2020 in EDC. Please review and clarify.' answered with '28JUL2020 is the correct date ' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 13:13:39
User opened query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however date is recorded as 28JUL2020 in EDC. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:21:18
Query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however there is no Unscheduled Visit date is recorded as 28JUL2020 in EDC. Please review and clarify.' canceled (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:20:57
User opened query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however there is no Unscheduled Visit date is recorded as 28JUL2020 in EDC. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:20:44
User entered '28 Jul 2020'	Morgan Deal (b) (4)	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Deal (b) (4)	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:40'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 14:40'	System	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 Morgan Deal (b) (4) (NASAL2)'		28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) [REDACTED]	28 Jul 2020 21:03:39

US3022052

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 21:03:39

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561'	System	28 Jul 2020 19:48:54
User entered 'Yes (Y)'	System	28 Jul 2020 19:48:54

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561' User entered '98.1'	System	28 Jul 2020 19:48:54

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561'	System	28 Jul 2020 19:48:54
User entered 'No (N)'	System	28 Jul 2020 19:48:54

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561'	System	28 Jul 2020 19:48:54
User entered '28 Jul 2020 15:48'	System	28 Jul 2020 19:48:54

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 15:34'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 18:04'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:13:59', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8'	System	29 Jul 2020 00:14:17
User entered 'Yes (Y)'	System	29 Jul 2020 00:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8'	System	29 Jul 2020 00:14:17
User entered '97.2'	System	29 Jul 2020 00:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8'	System	29 Jul 2020 00:14:17
User entered 'No (N)'	System	29 Jul 2020 00:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8'	System	29 Jul 2020 00:14:17
User entered '28 Jul 2020 20:14'	System	29 Jul 2020 00:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 18:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 2'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031'	System	29 Jul 2020 22:21:26
User entered 'Yes (Y)'	System	29 Jul 2020 22:21:26

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031'	System	29 Jul 2020 22:21:26
User entered '97.4'	System	29 Jul 2020 22:21:26

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:20', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031'	System	29 Jul 2020 22:21:26
User entered 'No (N)'	System	29 Jul 2020 22:21:26

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031'	System	29 Jul 2020 22:21:26
User entered '29 Jul 2020 18:21'	System	29 Jul 2020 22:21:26

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 3'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654'	System	30 Jul 2020 16:01:45
User entered 'Yes (Y)'	System	30 Jul 2020 16:01:45

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654'	System	30 Jul 2020 16:01:45
User entered '96.6'	System	30 Jul 2020 16:01:45

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654'	System	30 Jul 2020 16:01:45
User entered 'No (N)'	System	30 Jul 2020 16:01:45

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654'	System	30 Jul 2020 16:01:45
User entered '30 Jul 2020 12:01'	System	30 Jul 2020 16:01:45

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 4'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1'	System	31 Jul 2020 21:24:41
User entered 'Yes (Y)'	System	31 Jul 2020 21:24:41

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1' User entered '98.5'	System	31 Jul 2020 21:24:41

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1'	System	31 Jul 2020 21:24:41
User entered 'No (N)'	System	31 Jul 2020 21:24:41

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1'	System	31 Jul 2020 21:24:41
User entered '31 Jul 2020 17:24'	System	31 Jul 2020 21:24:41

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 5'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:53', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e'	System	02 Aug 2020 04:00:18
User entered 'Yes (Y)'	System	02 Aug 2020 04:00:18

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T00:00:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e'	System	02 Aug 2020 04:00:18
User entered '97.9'	System	02 Aug 2020 04:00:18

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T00:00:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e'	System	02 Aug 2020 04:00:18
User entered 'No (N)'	System	02 Aug 2020 04:00:18

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T00:00:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e'	System	02 Aug 2020 04:00:18
User entered '02 Aug 2020 00:00'	System	02 Aug 2020 04:00:18

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 6'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:13:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8'	System	02 Aug 2020 17:14:04
User entered 'Yes (Y)'	System	02 Aug 2020 17:14:04

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:13:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8'	System	02 Aug 2020 17:14:04
User entered '97.8'	System	02 Aug 2020 17:14:04

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:13:59', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8'	System	02 Aug 2020 17:14:04
User entered 'No (N)'	System	02 Aug 2020 17:14:04

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:02', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8'	System	02 Aug 2020 17:14:04
User entered '02 Aug 2020 13:14'	System	02 Aug 2020 17:14:04

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 7'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b'	System	04 Aug 2020 10:56:17
User entered 'Yes (Y)'	System	04 Aug 2020 10:56:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:56:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b' User entered '97.8'	System	04 Aug 2020 10:56:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:56:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b'	System	04 Aug 2020 10:56:17
User entered 'No (N)'	System	04 Aug 2020 10:56:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:56:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b'	System	04 Aug 2020 10:56:17
User entered '04 Aug 2020 06:56'	System	04 Aug 2020 10:56:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae'	System	28 Jul 2020 19:50:07
User entered 'None (1)'	System	28 Jul 2020 19:50:07

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae' User entered 'No (N)'	System	28 Jul 2020 19:50:07

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae'	System	28 Jul 2020 19:50:07
User entered 'No (N)'	System	28 Jul 2020 19:50:07

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:50:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae' User entered 'None (1)'	System	28 Jul 2020 19:50:07
	System	28 Jul 2020 19:50:07

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:50:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae' User entered '28 Jul 2020 15:50'	System	28 Jul 2020 19:50:07

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 15:34'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 18:04'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:20', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered 'None (1)'	System	29 Jul 2020 00:14:40

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered 'No (N)'	System	29 Jul 2020 00:14:40

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered 'No (N)'	System	29 Jul 2020 00:14:40

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered 'None (1)'	System	29 Jul 2020 00:14:40

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered '28 Jul 2020 20:14'	System	29 Jul 2020 00:14:40

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 18:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 2'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'None (1)'	System	29 Jul 2020 22:20:32

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'No (N)'	System	29 Jul 2020 22:20:32

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'No (N)'	System	29 Jul 2020 22:20:32

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'None (1)'	System	29 Jul 2020 22:20:32

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered '29 Jul 2020 18:20'	System	29 Jul 2020 22:20:32

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 3'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'None (1)'	System	30 Jul 2020 16:00:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'No (N)'	System	30 Jul 2020 16:00:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'No (N)'	System	30 Jul 2020 16:00:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'None (1)'	System	30 Jul 2020 16:00:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered '30 Jul 2020 12:00'	System	30 Jul 2020 16:00:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 4'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered 'None (1)'	System	31 Jul 2020 21:23:21

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered 'No (N)'	System	31 Jul 2020 21:23:21

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:11', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered 'No (N)'	System	31 Jul 2020 21:23:21

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered 'None (1)'	System	31 Jul 2020 21:23:21

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered '31 Jul 2020 17:23'	System	31 Jul 2020 21:23:21

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 5'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d'	System	02 Aug 2020 03:59:48
User entered 'None (1)'	System	02 Aug 2020 03:59:48

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:39', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d'	System	02 Aug 2020 03:59:48
User entered 'No (N)'	System	02 Aug 2020 03:59:48

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d'	System	02 Aug 2020 03:59:48
User entered 'No (N)'	System	02 Aug 2020 03:59:48

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d'	System	02 Aug 2020 03:59:48
User entered 'None (1)'	System	02 Aug 2020 03:59:48

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d'	System	02 Aug 2020 03:59:48
User entered '01 Aug 2020 23:59'	System	02 Aug 2020 03:59:48

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 6'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b'	System	02 Aug 2020 17:14:30
User entered 'None (1)'	System	02 Aug 2020 17:14:30

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:21', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b'	System	02 Aug 2020 17:14:30
User entered 'No (N)'	System	02 Aug 2020 17:14:30

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:22', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b'	System	02 Aug 2020 17:14:30
User entered 'No (N)'	System	02 Aug 2020 17:14:30

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b'	System	02 Aug 2020 17:14:30
User entered 'None (1)'	System	02 Aug 2020 17:14:30

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b'	System	02 Aug 2020 17:14:30
User entered '02 Aug 2020 13:14'	System	02 Aug 2020 17:14:30

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 7'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24'	System	04 Aug 2020 10:55:46
User entered 'None (1)'	System	04 Aug 2020 10:55:46

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24'	System	04 Aug 2020 10:55:46
User entered 'No (N)'	System	04 Aug 2020 10:55:46

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:39', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24'	System	04 Aug 2020 10:55:46
User entered 'No (N)'	System	04 Aug 2020 10:55:46

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24'	System	04 Aug 2020 10:55:46
User entered 'None (1)'	System	04 Aug 2020 10:55:46

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:45', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24'	System	04 Aug 2020 10:55:46
User entered '04 Aug 2020 06:55'	System	04 Aug 2020 10:55:46

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:11', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee'	System	28 Jul 2020 19:49:30
User entered 'None (0)'	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee'	System	28 Jul 2020 19:49:30
User entered 'None (0)'	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:18', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee'	System	28 Jul 2020 19:49:30
User entered 'None (0)'	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee'	System	28 Jul 2020 19:49:30
User entered 'No (N)'	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered '28 Jul 2020 15:49'	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 15:34'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 18:04'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered 'None (0)'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:45', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered 'None (0)'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered 'None (0)'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered 'None (0)'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered 'None (0)'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered 'None (0)'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:15:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered 'No (N)'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:15:02', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71'	System	29 Jul 2020 00:15:06
User entered '28 Jul 2020 20:15'	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 18:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 2'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b'	System	29 Jul 2020 22:20:50
User entered 'None (0)'	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b'	System	29 Jul 2020 22:20:50
User entered 'None (0)'	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b'	System	29 Jul 2020 22:20:50
User entered 'None (0)'	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b'	System	29 Jul 2020 22:20:50
User entered 'None (0)'	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b'	System	29 Jul 2020 22:20:50
User entered 'None (0)'	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b'	System	29 Jul 2020 22:20:50
User entered 'None (0)'	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b'	System	29 Jul 2020 22:20:50
User entered 'No (N)'	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered '29 Jul 2020 18:20'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 3'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered 'None (0)'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered 'None (0)'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered 'None (0)'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered 'None (0)'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered 'None (0)'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:34', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered 'None (0)'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered 'No (N)'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:39', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67'	System	30 Jul 2020 16:00:42
User entered '30 Jul 2020 12:00'	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 4'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered 'None (0)'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered 'None (0)'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered 'None (0)'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered 'None (0)'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered 'None (0)'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered 'None (0)'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered 'No (N)'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2'	System	31 Jul 2020 21:23:06
User entered '31 Jul 2020 17:23'	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 5'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:21', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered 'None (0)'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered 'None (0)'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered 'None (0)'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered 'None (0)'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered 'None (0)'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered 'None (0)'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered 'No (N)'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:34', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c'	System	02 Aug 2020 03:59:36
User entered '01 Aug 2020 23:59'	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 6'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered 'None (0)'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered 'None (0)'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered 'None (0)'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered 'None (0)'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered 'None (0)'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered 'None (0)'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered 'No (N)'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4'	System	02 Aug 2020 17:14:17
User entered '02 Aug 2020 13:14'	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 7'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:18', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df'	System	04 Aug 2020 10:55:36
User entered 'None (0)'	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df'	System	04 Aug 2020 10:55:36
User entered 'None (0)'	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:21', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df'	System	04 Aug 2020 10:55:36
User entered 'None (0)'	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df'	System	04 Aug 2020 10:55:36
User entered 'None (0)'	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df'	System	04 Aug 2020 10:55:36
User entered 'None (0)'	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df'	System	04 Aug 2020 10:55:36
User entered 'None (0)'	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df'	System	04 Aug 2020 10:55:36
User entered 'No (N)'	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered '04 Aug 2020 06:55'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:31:47

US3022052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:31:47

US3022052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:31:47

US3022052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:31:47

US3022052

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:02

US3022052

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 20:32:02

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:14

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:14

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:14

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:14

US3022052

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:19

US3022052

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 20:32:19

US3022052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:06:01

US3022052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:06:01

US3022052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Aug 2020 19:06:01

US3022052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:06:01

US3022052

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:06:05

US3022052

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 19:06:05

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:44:39

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:04:27
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'DATE IS CORRECT' (Site from System).	Shanice Bennett (b) (4)	24 Sep 2020 00:57:24
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Sep 2020 16:44:39
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:44:39

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 16:44:39

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	22 Sep 2020 16:44:39

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '15:58'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:58'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '131'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '17:16'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:16'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '89'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:39:02

US3022052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:39:02

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Chevon Roberts (b) (4) (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:46'	Chevon Roberts (b) (4) (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:46'	System	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Chevon Roberts (b) (4) (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:39:22

US3022052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:39:22

US3022052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:08'	(b) (4), (b) (6)	22 Sep 2020 17:39:22

US3022052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:08'	System	22 Sep 2020 17:39:22

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:41:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:39:44

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 17:39:44

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:39:44

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:21'	(b) (4), (b) (6)	22 Sep 2020 17:39:44

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:41:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:21'	System	22 Sep 2020 17:39:44

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 17:40:32

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 17:40:32

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:40:32

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:41:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 17:40:32

US3022052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:40:39

US3022052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 17:40:39

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:11:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5'	System	11 Sep 2020 21:15:06
User entered 'Yes (Y)'	System	11 Sep 2020 21:15:06

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:14:57', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5'	System	11 Sep 2020 21:15:06
User entered '98.8'	System	11 Sep 2020 21:15:06

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5'	System	11 Sep 2020 21:15:06
User entered 'No (N)'	System	11 Sep 2020 21:15:06

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:03', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5'	System	11 Sep 2020 21:15:06
User entered '11 Sep 2020 17:15'	System	11 Sep 2020 21:15:06

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:06'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 19:36'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:37:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695'	System	12 Sep 2020 13:38:07
User entered 'Yes (Y)'	System	12 Sep 2020 13:38:07

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:37:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695'	System	12 Sep 2020 13:38:07
User entered '98.7'	System	12 Sep 2020 13:38:07

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:01', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695'	System	12 Sep 2020 13:38:07
User entered 'No (N)'	System	12 Sep 2020 13:38:07

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695'	System	12 Sep 2020 13:38:07
User entered '12 Sep 2020 09:38'	System	12 Sep 2020 13:38:07

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 20:31'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 2'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:01:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da'	System	12 Sep 2020 16:06:48
User entered 'Yes (Y)'	System	12 Sep 2020 16:06:48

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:03', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da'	System	12 Sep 2020 16:06:48
User entered '98.4'	System	12 Sep 2020 16:06:48

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da'	System	12 Sep 2020 16:06:48
User entered 'No (N)'	System	12 Sep 2020 16:06:48

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da'	System	12 Sep 2020 16:06:48
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:06:48

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 3'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:00:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered 'Yes (Y)'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:01:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '96.8'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered 'Yes (Y)'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'attempted to reacg subject' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 20:44:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:01:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '1'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:01:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '0'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 4'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:01', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df'	System	14 Sep 2020 16:04:03
User entered 'Yes (Y)'	System	14 Sep 2020 16:04:03

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df'	System	14 Sep 2020 16:04:03
User entered '98.1'	System	14 Sep 2020 16:04:03

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df'	System	14 Sep 2020 16:04:03
User entered 'No (N)'	System	14 Sep 2020 16:04:03

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df'	System	14 Sep 2020 16:04:03
User entered '14 Sep 2020 12:01'	System	14 Sep 2020 16:04:03

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 5'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8'	System	16 Sep 2020 02:20:44
User entered 'Yes (Y)'	System	16 Sep 2020 02:20:44

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8'	System	16 Sep 2020 02:20:44
User entered '98.4'	System	16 Sep 2020 02:20:44

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8'	System	16 Sep 2020 02:20:44
User entered 'No (N)'	System	16 Sep 2020 02:20:44

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8'	System	16 Sep 2020 02:20:44
User entered '15 Sep 2020 22:20'	System	16 Sep 2020 02:20:44

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 6'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:30:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851'	System	16 Sep 2020 17:31:12
User entered 'Yes (Y)'	System	16 Sep 2020 17:31:12

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851'	System	16 Sep 2020 17:31:12
User entered '98.4'	System	16 Sep 2020 17:31:12

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851'	System	16 Sep 2020 17:31:12
User entered 'No (N)'	System	16 Sep 2020 17:31:12

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851'	System	16 Sep 2020 17:31:12
User entered '16 Sep 2020 13:31'	System	16 Sep 2020 17:31:12

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 7'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:11:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d'	System	17 Sep 2020 16:14:25
User entered 'Yes (Y)'	System	17 Sep 2020 16:14:25

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d'	System	17 Sep 2020 16:14:25
User entered '98.4'	System	17 Sep 2020 16:14:25

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d'	System	17 Sep 2020 16:14:25
User entered 'No (N)'	System	17 Sep 2020 16:14:25

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:22', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d'	System	17 Sep 2020 16:14:25
User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:14:25

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered 'None (1)'	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered 'No (N)'	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered 'No (N)'	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered 'None (1)'	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:30', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered '11 Sep 2020 17:15'	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:06'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 19:36'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a'	System	12 Sep 2020 13:38:53
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a'	System	12 Sep 2020 13:38:53
User entered 'No (N)'	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a'	System	12 Sep 2020 13:38:53
User entered 'No (N)'	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a'	System	12 Sep 2020 13:38:53
User entered 'None (1)'	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a' User entered '12 Sep 2020 09:38'	System	12 Sep 2020 13:38:53
	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 20:31'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 2'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f'	System	12 Sep 2020 16:08:08
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:22', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f'	System	12 Sep 2020 16:08:08
User entered 'No (N)'	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f'	System	12 Sep 2020 16:08:08
User entered 'No (N)'	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f'	System	12 Sep 2020 16:08:08
User entered 'None (1)'	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:30', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f'	System	12 Sep 2020 16:08:08
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 3'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered 'No (N)'	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered 'No (N)'	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered 'None (1)'	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 4'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c'	System	14 Sep 2020 16:02:23
User entered 'None (1)'	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c'	System	14 Sep 2020 16:02:23
User entered 'No (N)'	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c'	System	14 Sep 2020 16:02:23
User entered 'No (N)'	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c' User entered 'None (1)'	System	14 Sep 2020 16:02:23
	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:41', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c'	System	14 Sep 2020 16:02:23
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 5'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered 'None (1)'	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered 'No (N)'	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered 'No (N)'	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered 'None (1)'	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:57', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered '15 Sep 2020 22:20'	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 6'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6'	System	16 Sep 2020 17:31:23
User entered 'None (1)'	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6'	System	16 Sep 2020 17:31:23
User entered 'No (N)'	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6'	System	16 Sep 2020 17:31:23
User entered 'No (N)'	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6'	System	16 Sep 2020 17:31:23
User entered 'None (1)'	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6' User entered '16 Sep 2020 13:31'	System	16 Sep 2020 17:31:23
	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 7'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cadc979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'None (1)'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cad979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'No (N)'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cad979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'No (N)'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cadc979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'None (1)'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cad979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered 'None (0)'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered 'None (0)'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered 'None (0)'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered 'None (0)'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered 'None (0)'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered 'None (0)'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered 'No (N)'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509'	System	11 Sep 2020 21:10:51
User entered '11 Sep 2020 17:10'	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:06'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 19:36'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace'	System	12 Sep 2020 13:39:09
User entered 'None (0)'	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace'	System	12 Sep 2020 13:39:09
User entered 'None (0)'	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:57', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace'	System	12 Sep 2020 13:39:09
User entered 'None (0)'	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace'	System	12 Sep 2020 13:39:09
User entered 'None (0)'	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:02', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace'	System	12 Sep 2020 13:39:09
User entered 'None (0)'	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace'	System	12 Sep 2020 13:39:09
User entered 'None (0)'	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace'	System	12 Sep 2020 13:39:09
User entered 'No (N)'	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered '12 Sep 2020 09:39'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 20:31'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 2'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered 'None (0)'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered 'None (0)'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:41', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered 'None (0)'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered 'None (0)'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered 'None (0)'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered 'None (0)'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered 'No (N)'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:53', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6'	System	12 Sep 2020 16:08:52
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 3'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered 'None (0)'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered 'None (0)'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered 'None (0)'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered 'None (0)'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered 'None (0)'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered 'None (0)'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered 'No (N)'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:03:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d'	System	13 Sep 2020 16:03:20
User entered '13 Sep 2020 12:03'	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 4'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d'	System	14 Sep 2020 16:03:24
User entered 'None (0)'	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d'	System	14 Sep 2020 16:03:24
User entered 'None (0)'	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d'	System	14 Sep 2020 16:03:24
User entered 'None (0)'	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'None (0)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d'	System	14 Sep 2020 16:03:24
User entered 'None (0)'	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d'	System	14 Sep 2020 16:03:24
User entered 'None (0)'	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d'	System	14 Sep 2020 16:03:24
User entered 'No (N)'	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 5'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:01', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered 'None (0)'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:03', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered 'None (0)'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered 'None (0)'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered 'None (0)'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered 'None (0)'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:11', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered 'None (0)'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:15', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered 'No (N)'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:17', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71'	System	16 Sep 2020 02:21:20
User entered '15 Sep 2020 22:21'	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 6'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered 'None (0)'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered 'None (0)'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered 'None (0)'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered 'None (0)'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered 'None (0)'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered 'None (0)'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered 'No (N)'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94'	System	16 Sep 2020 17:31:40
User entered '16 Sep 2020 13:31'	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 7'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered 'None (0)'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered 'None (0)'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered 'None (0)'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered 'None (0)'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:41', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered 'None (0)'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered 'None (0)'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered 'No (N)'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8'	System	17 Sep 2020 16:14:51
User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:41:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:42:20

US3022052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:42:20

US3022052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 17:42:20

US3022052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:42:20

US3022052

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:42:25

US3022052

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 17:42:25

US3022052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:35:17

US3022052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 19:35:17

US3022052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 19:35:17

US3022052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 19:35:17

US3022052

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:35:22

US3022052

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 19:35:22

US3022052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:33:46

US3022052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 14:33:46

US3022052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 14:33:46

US3022052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:33:46

US3022052

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:33:51

US3022052

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 14:33:51

US3022052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:39:26

US3022052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:26

US3022052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 13:39:26

US3022052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	15 Oct 2020 13:39:26

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '09 Oct 2020 10:15'	System	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:40:00

US3022052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:40:00

US3022052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:40:12

US3022052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:40:12

US3022052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:32'	(b) (4), (b) (6)	15 Oct 2020 13:40:12

US3022052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 10:32'	System	15 Oct 2020 13:40:12

US3022052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:40:17

US3022052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 13:40:17

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 64'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-27T08:42:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e27c3fe-57b3-418a-b54c-4e5c8dfca952'	System	27 Sep 2020 12:42:58
User entered 'No (N)'	System	27 Sep 2020 12:42:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-27T08:42:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e27c3fe-57b3-418a-b54c-4e5c8dfca952'	System	27 Sep 2020 12:42:58
User entered 'No (N)'	System	27 Sep 2020 12:42:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-27T08:42:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e27c3fe-57b3-418a-b54c-4e5c8dfca952'	System	27 Sep 2020 12:42:58
User entered '27 Sep 2020 08:42:56'	System	27 Sep 2020 12:42:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '27 Sep 2020 00:01'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '01 Oct 2020 23:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 71'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-04T07:22:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5bf5c427-84ec-4bb0-80ff-3dfdcfce1848'	System	04 Oct 2020 11:22:36
User entered 'No (N)'	System	04 Oct 2020 11:22:36

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-04T07:22:30', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5bf5c427-84ec-4bb0-80ff-3dfdcfce1848'	System	04 Oct 2020 11:22:36
User entered 'No (N)'	System	04 Oct 2020 11:22:36

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-04T07:22:34', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5bf5c427-84ec-4bb0-80ff-3dfdcfce1848'	System	04 Oct 2020 11:22:36
User entered '04 Oct 2020 07:22:34'	System	04 Oct 2020 11:22:36

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '04 Oct 2020 00:01'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '08 Oct 2020 23:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 92'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T17:59:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069' User entered 'Yes (Y)'	System	28 Oct 2020 22:00:27
	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T17:59:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069'	System	28 Oct 2020 22:00:27
User entered 'No (N)'	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T17:59:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069' User entered 'No (N)'	System	28 Oct 2020 22:00:27
	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T18:00:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069' User entered 'No (N)'	System	28 Oct 2020 22:00:27
	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T18:00:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069' User entered '28 Oct 2020 18:00:24'	System	28 Oct 2020 22:00:27
	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '25 Oct 2020 00:01'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '29 Oct 2020 23:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 99'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:53', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'Yes (Y)'	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'No (N)'	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:45', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'No (N)'	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'Yes (Y)'	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Please 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:59', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered '04 Nov 2020 18:07:59'	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '01 Nov 2020 00:01'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '05 Nov 2020 23:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 106'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-10T12:07:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd53fa099-f65c-4c0c-acdc-fa53818d38ff'	System	10 Nov 2020 17:07:58
User entered 'No (N)'	System	10 Nov 2020 17:07:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-10T12:07:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd53fa099-f65c-4c0c-acdc-fa53818d38ff'	System	10 Nov 2020 17:07:58
User entered 'No (N)'	System	10 Nov 2020 17:07:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-10T12:07:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd53fa099-f65c-4c0c-acdc-fa53818d38ff' User entered '10 Nov 2020 12:07:56'	System	10 Nov 2020 17:07:58
	System	10 Nov 2020 17:07:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '08 Nov 2020 00:01'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '12 Nov 2020 23:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 113'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-17T12:45:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'aa80c738-3e7e-43a2-8e7c-10baa6252664'	System	17 Nov 2020 17:45:17
User entered 'No (N)'	System	17 Nov 2020 17:45:17

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-17T12:45:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'aa80c738-3e7e-43a2-8e7c-10baa6252664'	System	17 Nov 2020 17:45:17
User entered 'No (N)'	System	17 Nov 2020 17:45:17

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-17T12:45:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'aa80c738-3e7e-43a2-8e7c-10baa6252664' User entered '17 Nov 2020 12:45:14'	System	17 Nov 2020 17:45:17
	System	17 Nov 2020 17:45:17

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '15 Nov 2020 00:01'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '19 Nov 2020 23:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Sep 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Sep 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Oct 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Oct 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:28:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:28:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:28:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 22:51:22

US3022052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 22:51:22

US3022052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 22:51:22

US3022052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 22:51:22

US3022052

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 22:51:27

US3022052

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 22:51:27

US3022052

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:41:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:33
)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	05 Nov 2020 16:20:12
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 12:36:27
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:35
User entered 'USA-US051-2020-mRNA-1273-P301000010'	System	06 Nov 2020 16:48:27
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 16:48:27

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Oesophageal neoplasms malignant, PT: Oesophageal carcinoma, LLT: Esophageal cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:22:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:22:23
Data point term sent to Coder	System	05 Nov 2020 16:21:48
User entered 'Esophageal Cancer'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '15 Oct 2020'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:01:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'There is no end date for this as of yet.' (Site from Safety).	Morgan Deal (b) (4)	23 Nov 2020 18:30:24
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)	20 Nov 2020 18:20:39
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:10:12
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'will do' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:14:21
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)	12 Nov 2020 14:37:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Severity](#)

Audit	User	Time (GMT)
User closed query 'PV Query: If the subject was admitted to the hospital overnight, please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:10:35
Query 'PV Query: If the subject was admitted to the hospital overnight, please consider updating the severity of the event to Grade 4.' answered with 'The subject wasn't admitted ' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:14:40
User opened query 'PV Query: If the subject was admitted to the hospital overnight, please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:38:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 10:27:40
	(b) (4), (b) (6)	16 Nov 2020 01:59:56
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'subject wasn't hospitalized. PI wanted to submitted as an SAE due to Cancer diagnosis ' (Site from System).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:09
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). DataPoint Un-verified.	System	13 Nov 2020 13:15:30
	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
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	05 Nov 2020 16:22:56
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	05 Nov 2020 16:22:56
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	05 Nov 2020 16:21:44
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	05 Nov 2020 16:21:44

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1' reason for change: Data Entry Error	System	05 Nov 2020 16:21:44
	Shanice Bennett (b) (4)	05 Nov 2020 16:21:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	System	05 Nov 2020 16:21:09
	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:00:03
User closed query 'Please confirm patient was hospitalized - per source no.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:00:00
Query 'Please confirm patient was hospitalized - per source no.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:17:24
DataPoint Un-verified.	(b) (4)	
	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
	(b) (4), (b) (6)	
User opened query 'Please confirm patient was hospitalized - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:05:39
User entered '15 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	05 Nov 2020 16:22:56
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:10:54
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:00:06
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'subject wasn't hospitalized. PI wanted to submitted as an SAE due to Cancer diagnosis ' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:05
DataPoint Un-verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4)	
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.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:38:21
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)	12 Nov 2020 14:37:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:37:42
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:22:56
	(b) (4)	
	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '1'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Please confirm. Per source not applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:03
Query 'Please confirm. Per source not applicable.' answered with 'this is correct' (Site from CRA). DataPoint Verified.	Shanice Bennett (b) (4)	13 Nov 2020 13:16:57
	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:07:39
	(b) (4), (b) (6)	11 Nov 2020 15:06:44
User opened query 'Please confirm. Per source not applicable.' (Site from CRA).		
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 16:38:59
User entered '1'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 16:38:59
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:00:17
DataPoint Un-verified.	Shanice Bennett (b) (4)	13 Nov 2020 13:15:52
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Shanice Bennett (b) (4)	13 Nov 2020 13:15:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Outcome](#)

Audit	User	Time (GMT)
User closed 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)	24 Nov 2020 19:01:37
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.' answered with 'this event on going which needs to be not recovered/not resolved' (Site from Safety).	Morgan Deal (b) (4)	23 Nov 2020 18:32:41
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)	20 Nov 2020 18:20:24
User closed 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)	16 Nov 2020 16:13:38
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.' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:16:33
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)	12 Nov 2020 14:37:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per CDM CLR re-query: Response noted; however esophagectomy is not recorded in concomitant procedure. please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:34:10
User closed query 'Per CDM, per DM CLR re-query: Thank you for updating the Con Proc page. Please note that Esophagectomy has not been recorded. Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:28:17
Query 'Per CDM, per DM CLR re-query: Thank you for updating the Con Proc page. Please note that Esophagectomy has not been recorded. Kindly update as appropriate or clarify.' answered with 'Yes this updated on the con proc page' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 18:35:14
User opened query 'Per CDM, per DM CLR re-query: Thank you for updating the Con Proc page. Please note that Esophagectomy has not been recorded. Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:45:40
User closed query 'Per DM CLR: Narrative indicates that the subject had endoscopy, esophageal tissue biopsy, Esophagectomy and Gastrostomy Tube inserted for feeding. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:45:40
Query 'Per DM CLR: Narrative indicates that the subject had endoscopy, esophageal tissue biopsy, Esophagectomy and Gastrostomy Tube inserted for feeding. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:39:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject had endoscopy, esophageal tissue biopsy, Esophagectomy and Gastrostomy Tube inserted for feeding. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:18:49
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:11:34
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:11:27
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no COVID-19 test was done' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:16:23
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medication was added ' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:16:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:36:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Narrative](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:36:38
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Nov 2020 16:21:44
User entered 'Subject reported on day 85 safety phone call that he was diagnosed with esophageal cancer and has an upcoming surgery. Called and followed with patient. He reports over the past 3 years he has had difficulty in swallowing. He states he previously never sought care for this treated self for what he thought was acid reflux. Subject reports he had an endoscope on 15OCT2020 and had an esophageal tissue biopsied. He received the results of esophageal cancer and has surgery scheduled for 09Nov2020 for an esophagectomy and gastrostomy tube placed for feeding. He denies chemo or radiation planned at this time.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	05 Nov 2020 16:21:44
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Nov 2020 16:21:09
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 16:21:09

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 16:21:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:53
User closed query 'Per CDM: Per Diary Dose 2 (Temperature day), subject reports taking medication to treat pain/fever. Please confirm the medication details and record on the concomitant medication pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:49:06
Query 'Per CDM: Per Diary Dose 2 (Temperature day), subject reports taking medication to treat pain/fever. Please confirm the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 13:41:40
User opened query 'Per CDM: Per Diary Dose 2 (Temperature day), subject reports taking medication to treat pain/fever. Please confirm the medication details and record on the concomitant medication pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:45:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 12:11:33
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 12:36:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
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)	02 Oct 2020 12:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	02 Oct 2020 12:14:44
Data point term sent to Coder	System	02 Oct 2020 12:13:25
User entered 'metformin'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'type 2 diabetes'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '1000'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2014'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:12:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:40:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:40:44
Data point term sent to Coder	System	02 Oct 2020 12:13:25
User entered 'junuvia'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'type 2 diabetes'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '100'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2014'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
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)	02 Oct 2020 12:15:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:15:45
Data point term sent to Coder	System	02 Oct 2020 12:14:27
User entered 'lisinopril'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'hypertension'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '10'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2017'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:15:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:15:45
Data point term sent to Coder	System	02 Oct 2020 12:14:27
User entered 'rosuvastatin'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'hyperlipidemia'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '10'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2013'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
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 SODIUM, PRODUCTSYNONYM: LEVOTHYROXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:16:46
Data point term sent to Coder	System	02 Oct 2020 12:15:31
User entered 'levothyroxin'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'hypothyroidism'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '50'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'ug (ug)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2014'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:40:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:40:28
Data point term sent to Coder User entered 'IBUPROFEN'	System (b) (4), (b) (6)	15 Oct 2020 13:39:55 15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:07:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'no maae or sae ' (Site from DM).	Shanice Bennett (b) (4)	05 Nov 2020 16:30:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:05:51
User entered 'PAIN AT INJECTION SITE'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '200'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '13 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '13 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
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)	10 Nov 2020 14:02:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	10 Nov 2020 14:02:30
Data point term sent to Coder	System	10 Nov 2020 14:01:30
User entered 'Influenza VACCINE'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'PROPHYLAXIS'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0.5'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mL (mL)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once (ONCE)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:01:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:01:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:01:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:03:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:03:30
Data point term sent to Coder	System	10 Nov 2020 14:02:31
User entered 'PNEUMOCOCCAL VACCINE'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 14:01:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'PROPHYLAXIS'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0.5'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mL (mL)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once (ONCE)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:01:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:01:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:01:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: LANSOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:03:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:03:38
Data point term sent to Coder	System	10 Nov 2020 16:38:19
User entered 'lansoprazole'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'esophageal Cancer'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '30'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '02 Nov 2020'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:06
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:06

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:06

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:38:06

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:22:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:22:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
Data point term sent to Coder	System	10 Nov 2020 16:39:21
User entered 'Reglin'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'esophageal cancer'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '40'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '02 Nov 2020'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 16:38:34
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:41:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:41:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Query 'Please verify as AE notes concomitant procedure performed' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:41:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:38:48
User opened query 'Please verify as AE notes concomitant procedure performed' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 02:00:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 13:38:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 13:37:43
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 12:36:44

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:41:23

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Nov 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:37:02
User entered '15 Oct 2020'	Shanice Bennett (b) (4)	19 Nov 2020 20:39:19

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:41:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'esophageal tissue biopsy'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:39:19

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:39:19

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:41:23

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:39:19

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:41:23

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:46

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:41:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'gastrostomy tube'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:46

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:41:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:46

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:41:23

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:46

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:41:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User entered '06/Nov/2020 16:49'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:41:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:41:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User entered '11/Nov/2020 15:03'	System	11 Nov 2020 15:03:39

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:41:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 15:03:39

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

US3022052

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

US3022052

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[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

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Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

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[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

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[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 16:14'	System	16 Nov 2020 16:14:15

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:41:23

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 entered 'I'	(b) (4), (b) (6)	16 Nov 2020 16:14:15