

US3342343 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:58:36

All time stamps listed in this document are displayed in GMT

US3342343

Form: Participant Creation

Generated On: 26 Nov 2020 10:58:36

[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 10:58:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
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	True
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

Date of Informed Consent (<i>dd MMM yyyy</i>)	6 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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 10:58:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:58:36

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

Condition	HYSTERECTOMY (DUE TO UTERINE FIBROIDS)
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

Condition	FIBROIDS OF THE UTERUS
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

Condition	LEFT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

Condition	LEFT HIP SPORTS INDUCED INJURY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

Condition	HEADACHES
Start date (dd MMM yyyy)	06 SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:49 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 13:49
Height (<i>xxx.x</i>)	166.5 cm
Weight (<i>xxx.x</i>)	85.8 kg
BMI (<i>xxx.x</i>)	30.94987 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	51 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 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: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	UN UNK 1985
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Other	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Specify

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

What was the date of randomization? (dd MMM yyyy) 12 OCT 2020

What was the participant's randomization number? 116224

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:36

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 10:58:36

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)	12 OCT 2020
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:21
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 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 10:58:36

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)	12 OCT 2020
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 13:31
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 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 10:58:36

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)	12 OCT 2020
What was the treatment time? (00:00-23:59)	12:37 (24 HR)
Treatment Date and Time (derived)	12 OCT 2020 12:37
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input 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 10:58:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:17 (24 HR)
Collection date and time (derived)	12 OCT 2020 12:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:36

Collection date (<i>dd MMM yyyy</i>)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:20	12 OCT 2020 12:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

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 10:58:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

12 OCT 2020 13:35

PC Open Date & Time

12 OCT 2020 12:57

PC Close Date & Time

12 OCT 2020 15:27

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	13 OCT 2020 10:54
PC Open Date & Time	12 OCT 2020 16:22
PC Close Date & Time	13 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

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

96.8 °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

14 OCT 2020 10:00

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:58:36

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 11:22

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:58:36

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

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

17 OCT 2020 12:01

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

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

19 OCT 2020 10:26

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 13:36

PC Open Date & Time

12 OCT 2020 12:57

PC Close Date & Time

12 OCT 2020 15:27

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

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

13 OCT 2020 10:55

PC Open Date & Time

12 OCT 2020 16:22

PC Close Date & Time

13 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

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

14 OCT 2020 10:01

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

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

16 OCT 2020 11:22

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

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

17 OCT 2020 12:01

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

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

19 OCT 2020 10:27

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 13:38
PC Open Date & Time	12 OCT 2020 12:57
PC Close Date & Time	12 OCT 2020 15:27

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 10:56
PC Open Date & Time	12 OCT 2020 16:22
PC Close Date & Time	13 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

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 ☒

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 10:02
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

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 ☒

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 11:23
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

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 ☒

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 12:02
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

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 ☒

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 10:27
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 20 OCT 2020 09:10

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 21 OCT 2020 00:00

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 22 OCT 2020 01:00

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 23 OCT 2020 10:26

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 OCT 2020 09:10

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp	21 OCT 2020 00:00
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PC Open Date & Time	20 OCT 2020 12:00
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PC Close Date & Time	21 OCT 2020 11:59
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US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

22 OCT 2020 01:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 OCT 2020 09:10

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 OCT 2020 00:00

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 OCT 2020 01:00

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 OCT 2020 10:27

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 OCT 2020 22:35

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 OCT 2020 12:00

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	20 OCT 2020 09:10
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PC Open Date & Time	19 OCT 2020 12:00
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PC Close Date & Time	20 OCT 2020 11:59
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US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	21 OCT 2020 00:01
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PC Open Date & Time	20 OCT 2020 12:00
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PC Close Date & Time	21 OCT 2020 11:59
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US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 OCT 2020 01:00

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 OCT 2020 10:26

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 OCT 2020 22:35

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 25 OCT 2020 12:00

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 27 OCT 2020 09:14

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 09:11
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 00:01
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 01:00
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 10:26
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 22:35
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 12:00
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 OCT 2020 09:14
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

Was Contact Attempted?

Yes ☒

No ☐

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

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

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

CONTACT NOT MADE DUE TO
CONVALESCENT PERIOD.
SAFETY CALL DAY 15 WAS
SKIPPED.

US3342343

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

Was Contact Attempted?

Yes ☒

No ☐

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

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 NOV 2020
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	9 NOV 2020 09:33
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3342343

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 NOV 2020

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

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to ☐
Adverse Event ☐
Physician withheld dose due to ☒
Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	09 NOV 2020
Collection time (<i>00:00-23:59</i>)	10:43 (24 HR)
Collection date and time (derived)	09 NOV 2020 10:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:36

Collection date (<i>dd MMM yyyy</i>)			09 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	09 NOV 2020 10:45
Nasopharyngeal Swab 2	No		

US3342343

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

Was Contact Attempted?

Yes ☒

No ☐

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

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

Was Contact Attempted?

Yes ☒

No ☐

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

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342343

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 103

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

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

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 215

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

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

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 250

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	19 SEP 2021 23:59
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US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 <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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 <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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	13 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	20 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 <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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 <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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 <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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	04 SEP 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 ☐

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

Date and time of submission	
Patient Cloud Open Date & Time	23 NOV 2022 00:01
Patient Cloud Close Date & Time	27 NOV 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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 <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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

04 DEC 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

[Patient Cloud Close Date & Time](#)

11 DEC 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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="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"/>

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:58:36

Date of Contact	22 OCT 2020
Time of Contact	11:35
Date and Time of Contact (derived)	22 OCT 2020 11:35
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	325 of 1765	

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	329 of 1765	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	333 of 1765	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Nasal Congestion	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	337 of 1765	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	341 of 1765	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	345 of 1765	

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	349 of 1765	

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	353 of 1765	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	96.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	357 of 1765	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

Date of Visit	23 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	23 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:58:36

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:58:36

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	23 OCT 2020
Day 5	Yes	25 OCT 2020
Day 7	Yes	27 OCT 2020
Day 9	Yes	29 OCT 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:53 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:53
Height (<i>xxx.x</i>)	166.5 cm
Weight (<i>xxx.x</i>)	85.8 kg
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3342343

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:58:36

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3342343

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3342343

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:58:36

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3342343

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:58:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

AEID

Adverse event

WORSENING OF CERVICAL
DISC DISEASE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

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US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

WORSENING OF
OSTEOARTHRITIS OF THE
CERVICAL SPINE. SUBJECT
REPORTS INCREASED PAIN.
SHE SAW HER PHYSICIAN FOUR
WEEKS AGO FOR AN MRI AND
IS PLANNING A SURGERY.
REPORTS RECEIVING STEROID
INJECTION IN THE CERVICAL
SPINE 21 OCT 2020 BUT DOES
NOT RECALL THE DETAILS OF
THE MEDICATION (DRUG
NAME, DOSAGE) DUE TO
LANGUAGE BARRIER
BETWEEN SHE AND HER
PRIMARY CARE PHYSICIAN
WHO ADMINISTERED THE
TREATMENT,

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

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

AEID

Adverse event

NEW ONSET OF SYMMETRICAL
SYNOVITIS OF HANDS AND
FEET

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

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

Yes ☐
No ☒

Start date (dd MMM yyyy)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

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US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	SUBJECT REPORTS WORSENING OF OSTEOARTHRITIS IN HIPS, WRISTS, AND ANKLES FOR THE PAST 2 WEEKS. SHE REPORTS USING TORADOL TO TREAT.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

AEID

Adverse event

ACUTE VIRAL INFECTION-
FATIGUE, MUSCLE ACHES,
HEADACHE

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☒
No ☐

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

Yes ☐
No ☒

Start date (dd MMM yyyy)

18 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

27 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

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US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT REPORTED FATIGUE, MUSCLE ACHES, AND HA ONGOING PAST DAY 7 POST STUDY VACCINE ONE. BROUGHT IN FOR ILLNESS VISIT. COVID NEGATIVE. SYMPTOMS RESOLVED.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1

v6.020 DTW (1102)

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US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

Admitted to ICU Derived (CSA Programming Field Only)

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:58:36

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

Yes ☒

No ☐

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

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOARTHRITIS
Dose per administration	500
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"/>

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

Name of Medication	TORADOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOARTHRITIS
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 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 checked="" 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"/>

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

Name of Medication	CORTICOSTEROID
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>

Indication	OSTEOARTHRITIS
------------	----------------

Dose per administration	1
-------------------------	---

Dose unit	mg <input 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 checked="" type="radio"/>
-----------	--

If dose unit is Other, specify

DOSE *SUBJECT DID NOT
KNOW THE SPECIFIC DETAILS
OF THE STEROID INJECTION
(DRUG NAME, DOSAGE).
REPORTS LANGUAGE BARRIER
BETWEEN THEMSELVES AND
THEIR PRIMARY CARE
PHYSICIAN WHO
ADMINISTERED THE INJ.

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

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

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 type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	EPIDURAL	
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	21 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:58:36

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3342343

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:58:36

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

US3342343

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:58:36

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 ☐

Audit

US3342343 (Prod: Tekton Research- Austin)

US3342343

Form: Participant Creation

Generated On: 26 Nov 2020 10:58:36

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342343'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	06 Oct 2020 19:02:49

US3342343

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:19:32

US3342343

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '06 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	06 Oct 2020 19:02:51

US3342343

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:19:32

US3342343

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	06 Oct 2020 20:19:32

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Oct 2020 19:02:52

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Age](#)

Audit	User	Time (GMT)
User entered '61'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '61'	System	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

White

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

Unknown

Audit	User	Time (GMT)
User entered 'I'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:36

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2020'	System	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 4 (4)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Oct 2020 19:02:51

US3342343

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:58:36

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:58:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:21:12

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis spinal - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:24:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:24:27
Data point term sent to Coder	System	06 Oct 2020 20:23:39
User entered 'Osteoarthritis of the spine'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:15:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:15:48
Data point term sent to Coder	System	06 Oct 2020 20:24:45
User entered 'Hysterectomy (due to uterine fibroids)'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:26:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:26:22
Data point term sent to Coder	System	06 Oct 2020 20:25:47
User entered 'Fibroids of the uterus'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:28:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:28:17
Data point term sent to Coder	System	06 Oct 2020 20:27:55
User entered 'LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Tiffany Lemuz (b) (4) (b) (4)	06 Oct 2020 20:27:07
Data point term sent to Coder	System	06 Oct 2020 20:25:47
User entered 'Left hip knee replacement'	Tiffany Lemuz (b) (4) (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Sports injury, LLT: Sports injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 15:16:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 15:16:27
Data point term sent to Coder	System	06 Oct 2020 20:26:52
User entered 'Left hip sports induced injury'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:45:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:45:37
Data point term sent to Coder	System	23 Oct 2020 17:44:58
User entered 'Headaches'	Darrell O'Brien (b) (4) (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '06 Sep 2019'	Darrell O'Brien (b) (4) (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Sep 2019'	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2019'	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:49:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:49:27
Data point term sent to Coder	System	09 Nov 2020 21:13:38
User entered 'Osteoarthritis of bilateral hips and bilateral wrists'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2010'	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '13:49'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 13:49'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Height (xxx.x)

Audit	User	Time (GMT)
User entered '166.5' cm	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '85.8' kg	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '30.94987'	System	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 20:28:30
User entered '98.4' F reason for change: Data Entry Error	Tiffany Lemuz (b) (4) [REDACTED]	06 Oct 2020 20:28:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 20:28:23
User entered '98.4' (non-conformant).	Tiffany Lemuz (b) (4) [REDACTED]	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '51'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '146'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '93'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:57

US3342343

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:57

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Tiffany Lemuz (b) (4) [REDACTED] [REDACTED]	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:36

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '1'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:36

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Oct 2020 17:03:32

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '116224'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Oct 2020 17:03:32

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Oct 2020 17:03:32

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:52:20
DataPoint set to visible.	System	06 Oct 2020 20:20:56

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:36

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:36

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:36

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:36

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:31:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 17:31:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:08:33
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '11:21' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:21'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:36

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:36

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 18:43:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 18:43:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	12 Oct 2020 18:43:20
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:08:33
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '13:31' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 13:31'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '91' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:08:44

US3342343

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:08:44

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12:37'	Morgan Schulle (b) (4) (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:37'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Morgan Schulle (b) (4) (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:17'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:17'	System	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:20'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:20'	System	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:29:58

US3342343

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 17:29:58

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f'	System	12 Oct 2020 18:35:48
User entered 'Yes (Y)'	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:31', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f'	System	12 Oct 2020 18:35:48
User entered '97.1'	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f'	System	12 Oct 2020 18:35:48
User entered 'No (N)'	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:46', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f' User entered '12 Oct 2020 13:35'	System	12 Oct 2020 18:35:48
	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:57'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 15:27'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:18', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018'	System	13 Oct 2020 15:54:45
User entered 'Yes (Y)'	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:26', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018'	System	13 Oct 2020 15:54:45
User entered '97.8'	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018'	System	13 Oct 2020 15:54:45
User entered 'No (N)'	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018'	System	13 Oct 2020 15:54:45
User entered '13 Oct 2020 10:54'	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 16:22'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 2'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:07', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered 'Yes (Y)'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered '96.8'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered 'No (N)'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:34', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered '14 Oct 2020 10:00'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 3'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 4'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:20:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered 'Yes (Y)'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:14', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered '96.8'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered 'No (N)'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered '16 Oct 2020 11:22'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 5'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 6'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:00:41', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered 'Yes (Y)'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:00:58', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered '97.8'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:03', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered 'No (N)'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 7'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:25:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered 'Yes (Y)'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:26:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered '97.8'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:26:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered 'No (N)'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:26:31', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered '19 Oct 2020 10:26'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[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 (1858609a30306a15)', Time: '2020-10-12T13:36:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:34', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'No (N)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'No (N)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[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 (1858609a30306a15)', Time: '2020-10-12T13:36:55', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'None (1)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:59', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered '12 Oct 2020 13:36'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:57'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 15:27'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[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 (1858609a30306a15)', Time: '2020-10-13T10:55:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'None (1)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'No (N)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:33', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'No (N)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-13T10:55:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'None (1)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:52', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered '13 Oct 2020 10:55'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 16:22'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 2'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

[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 (1858609a30306a15)', Time: '2020-10-14T10:00:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'None (1)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:59', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'No (N)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:11', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'No (N)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-14T10:01:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'None (1)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:19', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered '14 Oct 2020 10:01'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 3'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 4'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

[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 (1858609a30306a15)', Time: '2020-10-16T11:22:36', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'None (1)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'No (N)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'No (N)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-16T11:22:52', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'None (1)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered '16 Oct 2020 11:22'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 5'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 6'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

[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 (1858609a30306a15)', Time: '2020-10-17T12:01:33', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'None (1)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:37', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'No (N)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'No (N)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

[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 (1858609a30306a15)', Time: '2020-10-17T12:01:49', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'None (1)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:52', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 7'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-19T10:26:58', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'None (1)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:02', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'No (N)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'No (N)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-19T10:27:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'None (1)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:14', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered '19 Oct 2020 10:27'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:37:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'None (0)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:37:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:37:49', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:04', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'None (0)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:08', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'None (0)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-12T13:38:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No (N)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered '12 Oct 2020 13:38'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:57'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 15:27'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:10', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'No interference with activity (1)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'No interference with activity (1)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'Some interference with activity (2)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'Some interference with activity (2)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:30', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'None (0)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:34', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'None (0)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-13T10:56:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'No (N)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered '13 Oct 2020 10:56'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 16:22'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 2'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'None (0)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No interference with activity (1)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:36', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No interference with activity (1)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:41', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No interference with activity (1)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'None (0)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:48', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'None (0)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-14T10:01:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No (N)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:02:01', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered '14 Oct 2020 10:02'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 3'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 4'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:23', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'Some interference with activity (2)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'Some interference with activity (2)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'None (0)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'None (0)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-16T11:23:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'No (N)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:45', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered '16 Oct 2020 11:23'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 5'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 6'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:58', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:17', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:21', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-17T12:02:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'No (N)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:38', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered '17 Oct 2020 12:02'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 7'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:26', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:30', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:36', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'None (0)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'None (0)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-19T10:27:51', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No (N)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered '19 Oct 2020 10:27'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 8'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '73c10057-1cb7-424a-92dc-69f92898d3a8'	System	20 Oct 2020 14:10:35
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '73c10057-1cb7-424a-92dc-69f92898d3a8' User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:35
	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:23', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3d902b18-4aa6-4576-882e-389dcb7dc0da'	System	21 Oct 2020 05:00:35
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:31', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3d902b18-4aa6-4576-882e-389dcb7dc0da'	System	21 Oct 2020 05:00:35
User entered '21 Oct 2020 00:00'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 14:10:35
User entered 'Day 10'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e92905d-1ab1-4aaa-87c3-be7009f60423'	System	22 Oct 2020 06:00:11
User entered 'No interference with activity (1)'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e92905d-1ab1-4aaa-87c3-be7009f60423'	System	22 Oct 2020 06:00:11
User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 05:00:35
User entered 'Day 11'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:45', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f9d27080-e837-473f-922b-303c56295e25'	System	23 Oct 2020 15:26:50
User entered 'None (0)'	System	23 Oct 2020 15:26:50

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:48', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f9d27080-e837-473f-922b-303c56295e25'	System	23 Oct 2020 15:26:50
User entered '23 Oct 2020 10:26'	System	23 Oct 2020 15:26:50

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 8'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'db006a87-97ad-4267-a5b2-e2d956ee6648'	System	20 Oct 2020 14:10:46
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'db006a87-97ad-4267-a5b2-e2d956ee6648'	System	20 Oct 2020 14:10:46
User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5a04fdca-7ac1-43ca-8dc4-a7f500e49e54'	System	21 Oct 2020 05:00:48
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:42', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5a04fdca-7ac1-43ca-8dc4-a7f500e49e54'	System	21 Oct 2020 05:00:48
User entered '21 Oct 2020 00:00'	System	21 Oct 2020 05:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 14:10:46
User entered 'Day 10'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:21', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e188cf7-7aeb-4fd0-81a5-73e80dbdd342'	System	22 Oct 2020 06:00:27
User entered 'None (0)'	System	22 Oct 2020 06:00:27

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e188cf7-7aeb-4fd0-81a5-73e80dbdd342'	System	22 Oct 2020 06:00:27
User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:27

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 17:02:41
User entered 'Day 8'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b0f40ce5-a1a3-4845-8ebe-ef7d35e8ee88'	System	20 Oct 2020 14:10:24
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:20', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b0f40ce5-a1a3-4845-8ebe-ef7d35e8ee88'	System	20 Oct 2020 14:10:24
User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '6341b837-2397-4ac8-84a8-e14ee9614523'	System	21 Oct 2020 05:00:54
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:50', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '6341b837-2397-4ac8-84a8-e14ee9614523'	System	21 Oct 2020 05:00:54
User entered '21 Oct 2020 00:00'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 14:10:24
User entered 'Day 10'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:29', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7fa61ff3-016b-40b1-b33b-a6e019dd0acc'	System	22 Oct 2020 06:00:34
User entered 'No interference with activity (1)'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7fa61ff3-016b-40b1-b33b-a6e019dd0acc'	System	22 Oct 2020 06:00:34
User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 05:00:54
User entered 'Day 11'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:54', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c6d164c0-de54-48fe-a730-443e0f8ada08'	System	23 Oct 2020 15:27:10
User entered 'No interference with activity (1)'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:27:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c6d164c0-de54-48fe-a730-443e0f8ada08'	System	23 Oct 2020 15:27:10
User entered '23 Oct 2020 10:27'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 06:00:34
User entered 'Day 12'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c59a35d9-7ac8-4b2c-b1d8-d227fe21a44c'	System	24 Oct 2020 03:35:41
User entered 'No interference with activity (1)'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:38', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c59a35d9-7ac8-4b2c-b1d8-d227fe21a44c'	System	24 Oct 2020 03:35:41
User entered '23 Oct 2020 22:35'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 15:27:10
User entered 'Day 13'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 03:35:41
User entered 'Day 14'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:25', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd3001cb4-c8e3-4d67-8e77-6d33398f642d'	System	25 Oct 2020 17:00:38
User entered 'None (0)'	System	25 Oct 2020 17:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd3001cb4-c8e3-4d67-8e77-6d33398f642d'	System	25 Oct 2020 17:00:38
User entered '25 Oct 2020 12:00'	System	25 Oct 2020 17:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 17:02:41
User entered 'Day 8'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:50', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '12f5ba82-6d7a-440c-a21f-b29ddceea297'	System	20 Oct 2020 14:10:59
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:55', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '12f5ba82-6d7a-440c-a21f-b29ddceea297'	System	20 Oct 2020 14:10:59
User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:55', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b7c7f0a-a73d-470e-a71c-bd83fb290c53'	System	21 Oct 2020 05:01:09
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:01:04', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b7c7f0a-a73d-470e-a71c-bd83fb290c53'	System	21 Oct 2020 05:01:09
User entered '21 Oct 2020 00:01'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 14:10:59
User entered 'Day 10'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:38', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a4248cdb-d2ec-43b2-ab2e-9b55f713c1bd'	System	22 Oct 2020 06:00:48
User entered 'No interference with activity (1)'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a4248cdb-d2ec-43b2-ab2e-9b55f713c1bd'	System	22 Oct 2020 06:00:48
User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 05:01:09
User entered 'Day 11'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:07', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '54a11abe-1a07-4a72-bfd9-f5a9720deb67'	System	23 Oct 2020 15:26:15
User entered 'No interference with activity (1)'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '54a11abe-1a07-4a72-bfd9-f5a9720deb67'	System	23 Oct 2020 15:26:15
User entered '23 Oct 2020 10:26'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 06:00:48
User entered 'Day 12'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:45', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0223171f-71a4-45a1-8dba-eb08ce0e9890'	System	24 Oct 2020 03:35:52
User entered 'No interference with activity (1)'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:49', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0223171f-71a4-45a1-8dba-eb08ce0e9890'	System	24 Oct 2020 03:35:52
User entered '23 Oct 2020 22:35'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 15:26:15
User entered 'Day 13'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 03:35:52
User entered 'Day 14'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:33', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '632dcdfc-0fa8-4d7a-b373-d078a9d2b878'	System	25 Oct 2020 17:00:43
User entered 'No interference with activity (1)'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '632dcdfc-0fa8-4d7a-b373-d078a9d2b878'	System	25 Oct 2020 17:00:43
User entered '25 Oct 2020 12:00'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 17:00:43
User entered 'Day 15'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:58:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-27T09:13:59', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '2ae36ada-a1b7-4e3d-b121-fddd0765ceae'	System	27 Oct 2020 14:14:06
User entered 'None (0)'	System	27 Oct 2020 14:14:06

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-27T09:14:02', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '2ae36ada-a1b7-4e3d-b121-fddd0765ceae'	System	27 Oct 2020 14:14:06
User entered '27 Oct 2020 09:14'	System	27 Oct 2020 14:14:06

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 17:02:41
User entered 'Day 8'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-20T09:11:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f807875f-5a08-4fa4-b0cf-4b8968aad014'	System	20 Oct 2020 14:11:09
User entered 'No (N)'	System	20 Oct 2020 14:11:09

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:11:03', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f807875f-5a08-4fa4-b0cf-4b8968aad014'	System	20 Oct 2020 14:11:09
User entered '20 Oct 2020 09:11'	System	20 Oct 2020 14:11:09

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-21T00:01:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7ed5749d-a6c6-402a-9bc9-1f0d153f809f'	System	21 Oct 2020 05:01:16
User entered 'No (N)'	System	21 Oct 2020 05:01:16

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:01:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7ed5749d-a6c6-402a-9bc9-1f0d153f809f' User entered '21 Oct 2020 00:01'	System	21 Oct 2020 05:01:16
	System	21 Oct 2020 05:01:16

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 14:10:24
User entered 'Day 10'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-22T01:00:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '29d52f6f-a3f6-4462-b1c0-4aaa95e94d1b'	System	22 Oct 2020 06:00:54
User entered 'No (N)'	System	22 Oct 2020 06:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:50', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '29d52f6f-a3f6-4462-b1c0-4aaa95e94d1b'	System	22 Oct 2020 06:00:54
User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 05:00:35
User entered 'Day 11'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-23T10:26:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '439d4ec3-e925-4f7c-89a5-e5d4382c7f6c'	System	23 Oct 2020 15:26:23
User entered 'No (N)'	System	23 Oct 2020 15:26:23

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:21', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '439d4ec3-e925-4f7c-89a5-e5d4382c7f6c'	System	23 Oct 2020 15:26:23
User entered '23 Oct 2020 10:26'	System	23 Oct 2020 15:26:23

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 06:00:11
User entered 'Day 12'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-23T22:35:53', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1a8bdece-4f2d-4819-922a-54a81dae43e0'	System	24 Oct 2020 03:35:58
User entered 'No (N)'	System	24 Oct 2020 03:35:58

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1a8bdece-4f2d-4819-922a-54a81dae43e0'	System	24 Oct 2020 03:35:58
User entered '23 Oct 2020 22:35'	System	24 Oct 2020 03:35:58

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 15:26:15
User entered 'Day 13'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 03:35:41
User entered 'Day 14'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-25T12:00:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cb5af3ad-8c6d-4499-8428-1071c703e93d'	System	25 Oct 2020 17:00:50
User entered 'No (N)'	System	25 Oct 2020 17:00:50

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:42', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cb5af3ad-8c6d-4499-8428-1071c703e93d'	System	25 Oct 2020 17:00:50
User entered '25 Oct 2020 12:00'	System	25 Oct 2020 17:00:50

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 17:00:43
User entered 'Day 15'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:58:36

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 (1858609a30306a15)', Time: '2020-10-27T09:14:06', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c561d88b-83a3-4cec-8729-b76a5353645a'	System	27 Oct 2020 14:14:11
User entered 'No (N)'	System	27 Oct 2020 14:14:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:58:36

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-27T09:14:08', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c561d88b-83a3-4cec-8729-b76a5353645a'	System	27 Oct 2020 14:14:11
User entered '27 Oct 2020 09:14'	System	27 Oct 2020 14:14:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:58:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:58:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 17:00:43

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	20 Oct 2020 17:55:37

US3342343

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 17:55:37

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	04 Nov 2020 20:33:16
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	02 Nov 2020 23:25:17
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	02 Nov 2020 23:25:17

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Nov 2020 20:21:07
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:21:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Nov 2020 23:27:20
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Nov 2020 23:27:20
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	02 Nov 2020 23:27:20
User entered ' 2020' (non-conformant).	Ethan Shotton (b) (4) (b) (4)	02 Nov 2020 23:27:20
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Nov 2020 23:25:17
User entered '2 Nov 2020'	Ethan Shotton (b) (4) (b) (4)	02 Nov 2020 23:25:17

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4)	04 Nov 2020 20:33:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	Ethan Shotton (b) (4)	02 Nov 2020 23:25:17

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'CONTACT NOT MADE DUE TO CONVALESCENT PERIOD. SAFETY CALL DAY 15 WAS SKIPPED.' reason for change: Data Entry Error	Ethan Shotton (b) (4)	04 Nov 2020 20:22:39
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	02 Nov 2020 23:27:20
User entered 'Contact not made due to convalescent period' reason for change: Data Entry Error	Ethan Shotton (b) (4)	02 Nov 2020 23:27:20
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	02 Nov 2020 23:25:17
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 23:25:17

US3342343

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	02 Nov 2020 23:28:20

US3342343

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 23:28:20

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:41

US3342343

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 20:24:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '09:33'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '9 Nov 2020 09:33'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.0' F	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '14'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

If No, reason not given

Audit	User	Time (GMT)
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:43'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 10:43'	System	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:45'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 10:45'	System	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 21:12:27

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Ethan Shotton (b) (4) (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	16 Nov 2020 20:47:14

US3342343

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 20:47:14

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 22:44:02

US3342343

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 22:44:02

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Dec 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Dec 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Dec 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Dec 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:58:36

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:58:36

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '11:35'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:58:36

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:35'	System	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:58:36

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:58:36

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:16:33

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96' reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 16:24:12
User entered empty.	System	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96' reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 16:24:12
User entered empty.	System	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96' reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 16:26:15
User entered empty.	System	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96' reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 16:26:15
User entered empty.	System	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Eileen Euperio (b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.4' F	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.0' F	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Date](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.0' F	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:58:36

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[Date of Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab recon: Swab: Sample collection date 23-OCT-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in GCL. Kindly confirm if swab sample was collected on 23-OCT-2020 for Covid-19 Assessment visit to be updated in GCL records.' (Site from DM). User entered '23 Oct 2020'	(b) (4), (b) (6) Eileen Euperio (b) (4) (b) (4)	13 Nov 2020 04:36:47 05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[Date of Test](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (NasopharyngealEileen Euperio Swab)'	(b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:58:36

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:58:36

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:23

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:58:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:58:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:58:36

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the same is reported with date 24OCT2020 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)	06 Nov 2020 12:48:12
User entered '23 Oct 2020'	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:58:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:58:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:58:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:58:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:58:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:58:36

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is recorded under Illness Visit Day 7 visit in EDC, however the same is reported with date 28OCT2020 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)	06 Nov 2020 12:54:37
User entered '27 Oct 2020'	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:58:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:58:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:58:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:58:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:58:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:58:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:58:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:58:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:58:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:58:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:58:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:58:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 22 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User entered '22 Oct 2020'	(b) (4), (b) (6) [REDACTED] [REDACTED] Darrell O'Brien (b) (4) [REDACTED]	09 Nov 2020 13:17:12 22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '11:53'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:53'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '166.5' cm	Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13
DataPoint set to visible.	(b) (4) System	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '85.8' kg	Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13
DataPoint set to visible.	(b) (4) System	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

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

Audit	User	Time (GMT)
User entered '12'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '131'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:27

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:04:27

US3342343

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:58:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 20:56:24

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc disorder, LLT: Cervical disc disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:12:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:12:41
Data point term sent to Coder	System	09 Nov 2020 21:01:09
User entered 'Worsening of cervical disc disease'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	09 Nov 2020 21:01:31
User entered '19 Oct 2020' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	09 Nov 2020 21:01:31
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	09 Nov 2020 21:00:28
User entered '09 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[None](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Worsening of osteoarthritis of the cervical spine. Subject reports increased pain. She saw her physician four weeks ago for an MRI and is planning a surgery. Reports receiving steroid injection in the cervical spine 21 Oct 2020 but does not recall the details of the medication (drug name, dosage) due to language barrier between she and her primary care physician who administered the treatment,'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovitis, LLT: Synovitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:59:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:59:37
Data point term sent to Coder	System	09 Nov 2020 21:05:16
User entered 'New onset of symmetrical synovitis of hands and feet'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Tiffany Lemuz (b) (4) [REDACTED] [REDACTED]	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[None](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reports worsening of osteoarthritis in hips, wrists, and ankles for the past 2 weeks. She reports using Toradol to treat.'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:58:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please provide symptoms.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:57:16
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:36:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:36:11
Data point term sent to Coder	System	23 Nov 2020 22:42:07
Query 'Per MM: Please provide symptoms.' answered with 'Symptoms provided ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:42:00
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 22:41:49
User entered 'ACUTE VIRAL INFECTION-Fatigue, Muscle Aches, headache' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 22:41:49
User opened query 'Per MM: Please provide symptoms.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:16:57
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:18:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:18:37
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:09:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:09:38
Data point term sent to Coder	System	09 Nov 2020 21:08:32
User entered 'Acute viral infection'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Oct 2020' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	09 Nov 2020 21:09:09
User entered '13 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:09:09
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:07:38
User entered empty.	Tiffany Lemuz (b) (4) [REDACTED] [REDACTED]	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:09:09
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:07:38
User entered empty.	Tiffany Lemuz (b) (4) [REDACTED] [REDACTED]	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 21:09:18
User entered '1' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	09 Nov 2020 21:09:18
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 21:07:38
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported fatigue, muscle aches, and HA ongoing past day 7 post study vaccine one. Brought in for illness visit. COVID negative. Symptoms resolved.'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:58:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 21:07:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:58:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:53

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:15:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:15:37
Data point term sent to Coder	System	09 Nov 2020 21:14:40
User entered 'Ibuprofen'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Indication](#)

Audit	User	Time (GMT)
User entered 'Osteoarthritis'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:30:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:30:41
Data point term sent to Coder	System	09 Nov 2020 21:15:41
User entered 'Toradol'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Indication](#)

Audit	User	Time (GMT)
User entered 'Osteoarthritis'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:53:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:53:42
Data point term sent to Coder	System	09 Nov 2020 21:20:49
User entered 'Corticosteroid'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Indication](#)

Audit	User	Time (GMT)
User entered 'Osteoarthritis'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'dose *Subject did not know the specific details of the steroid injection (drug name, dosage). Reports language barrier between themselves and their primary care physician who administered the inj.'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'Epidural'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:58:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:20:18