

US3362210 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:12:51

All time stamps listed in this document are displayed in GMT

US3362210

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:33:16

Generated On: 09 Jun 2021 17:12:51

[Participant ID](#)

US3362210

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

US3362210

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3362210

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3362210

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3362210

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3362210

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Were any significant conditions reported?

Yes ☒

No ☐

US3362210

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Condition	BARRETT'S ESOPHAGUS DYSPLASIA
Start date (dd MMM yyyy)	21 SEP 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3362210

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	
Stop Year (derived)	

US3362210

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	14 JUN 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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3362210

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Condition	RIGHT FOOT FRACTURE
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3362210

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Condition	RIGHT FOOT INFECTION
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3362210

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Condition	RIGHT FOOT SKIN GRAFT
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3362210

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Condition	GERD (ACID REFLUX)
Start date (dd MMM yyyy)	UN UNK 2015
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)	29 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

US3362210

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	07:55 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 07:55
Height (<i>xxx.x</i>)	181 cm
Weight (<i>xxx.x</i>)	108.7 kg
BMI (<i>xxx.x</i>)	33.17970 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362210

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3362210

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify

FACILITY MAINTENANCE
MANAGER FROM (b) (6)
STORE THROUGHOUT LA, AND
MS.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

PRODUCTION RELEASE (v12.003
EAB) (1725)

16 of 2694

US3362210

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:22:41

Generated On: 09 Jun 2021 17:12:51

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
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	NEPHEW IS EKG TECH (b) (6) SPOUSE STAYS AT HOME

US3362210

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 144582

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 ☒

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Height	ND - Not Done
Weight	ND - Not Done

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

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)	21 AUG 2020
Time of assessment (00:00-23:59)	07:55 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 07:55
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	09:38 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 09:38
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3362210

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 AUG 2020

What was the treatment time? (00:00-23:59) 09:01 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 09:01

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

What was the frequency of the study treatment dosing? ONCE

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

US3362210

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	08:32 (24 HR)
Collection date and time (derived)	21 AUG 2020 08:32

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:30	21 AUG 2020 08:30
Nasopharyngeal Swab 2	No		

US3362210

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 09:35

PC Open Date & Time

21 AUG 2020 09:21

PC Close Date & Time

21 AUG 2020 11:51

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

100.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp	21 AUG 2020 19:06
PC Open Date & Time	21 AUG 2020 12:46
PC Close Date & Time	22 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

100.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:51

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

100.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 18:52

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 18:59

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 18:50

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 09:36

PC Open Date & Time

21 AUG 2020 09:21

PC Close Date & Time

21 AUG 2020 11:51

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

21 AUG 2020 19:07

PC Open Date & Time

21 AUG 2020 12:46

PC Close Date & Time

22 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

22 AUG 2020 19:03

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 18:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

24 AUG 2020 19:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 18:53

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

26 AUG 2020 18:59

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

27 AUG 2020 18:50

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 09:37
PC Open Date & Time	21 AUG 2020 09:21
PC Close Date & Time	21 AUG 2020 11:51

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 19:08
PC Open Date & Time	21 AUG 2020 12:46
PC Close Date & Time	22 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

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 ☒

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:04
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:52
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

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 ☒

PRODUCTION RELEASE (v12.003

52 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:19
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:53
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 18:59
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:50
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3362210

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 SEP 2020

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

Comments PT WAS IN CONVALESCENT
PERIOD SAFETY CALL TIME
If Contact Not Made, please provide Comments FRAME DURING SAFETY DAY
15

US3362210

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

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)	22 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 10:00
Temperature (xxx.x)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

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)	22 SEP 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 11:20
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3362210

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 SEP 2020

What was the treatment time? (00:00-23:59) 10:47 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 10:47

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

What was the frequency of the study treatment dosing? ONCE

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

US3362210

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

10:16 (24 HR)

Collection date and time (derived)

22 SEP 2020 10:16

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:14	22 SEP 2020 10:14
Nasopharyngeal Swab 2	No		

US3362210

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 11:21

PC Open Date & Time

22 SEP 2020 11:07

PC Close Date & Time

22 SEP 2020 13:37

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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 99.2 °F

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

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

PC Time Stamp	22 SEP 2020 18:21
PC Open Date & Time	22 SEP 2020 14:32
PC Close Date & Time	23 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 18:33

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 15:04

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

99.1 °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

25 SEP 2020 18:41

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 17:27

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 16:51

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

28 SEP 2020 16:26

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 11:21

PC Open Date & Time

22 SEP 2020 11:07

PC Close Date & Time

22 SEP 2020 13:37

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

22 SEP 2020 18:22

PC Open Date & Time

22 SEP 2020 14:32

PC Close Date & Time

23 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

23 SEP 2020 18:33

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 15:04

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

25 SEP 2020 18:41

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 17:27

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

27 SEP 2020 16:51

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

28 SEP 2020 16:26

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 11:22
PC Open Date & Time	22 SEP 2020 11:07
PC Close Date & Time	22 SEP 2020 13:37

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 18:22
PC Open Date & Time	22 SEP 2020 14:32
PC Close Date & Time	23 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 18:33
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 15:04
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

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 ☒

PRODUCTION RELEASE (v12.003

98 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:41
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

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 ☒

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 17:27
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

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 ☒

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 16:51
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

104 of 2694

EAB) (1725)

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 16:26
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3362210

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 13:19
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362210

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3362210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

13:14 (24 HR)

Collection date and time (derived)

23 OCT 2020 13:14

US3362210

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:16:39

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 07:20:38

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 12:31:11

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:38:19

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 06:44:20

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 07:58:24
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 12:09:07

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 08:01:58

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 07:12:41

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 06:09:15
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 06:37:03

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 08:55:14

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	True
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 JAN 2021 08:34:53
Patient Cloud Open Date & Time	10 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
128 of 2694	

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 08:25:43

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 07:38:32

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 06:43:57

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 12:10:37

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 07:09:54
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 04:49:00

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 12:08:41

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 06:13:59
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 12:30:32

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

21 MAR 2021 06:41:16

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 06:45:45

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 20:21:36

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 06:42:26
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 06:04:22

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:42:41

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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°F/38°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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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="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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 <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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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="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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

Patient Cloud Open Date & Time	14 NOV 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	18 NOV 2021 23:59
---	-------------------

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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="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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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="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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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="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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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="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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 768

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3362210

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:12:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 02:37:15

US3362210

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:24:55

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:24:55

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3362210

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

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.

US3362210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

12:38 (24 HR)

Collection date and time (derived)

19 MAR 2021 12:38

US3362210

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362210

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362210

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:33:35

Generated On: 09 Jun 2021 17:12:51

Date of Contact	12 JAN 2021
Time of Contact	12:45
Date and Time of Contact (derived)	12 JAN 2021 12:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Symptom Day

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	8 JAN 2021	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

322 of 2694

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	9 JAN 2021	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

325 of 2694

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	10 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

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"/>

PRODUCTION RELEASE (v12.003

329 of 2694

EAB) (1725)

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	11 JAN 2021	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 2694

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	36.8 C	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

337 of 2694

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 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 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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.7 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

341 of 2694

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.9 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

345 of 2694

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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 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 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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	15 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 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"/>
PRODUCTION RELEASE (v12.003	349 of 2694	
EAB) (1725)		

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	16 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

353 of 2694

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:33:35

Generated On: 09 Jun 2021 17:12:51

Date of Visit	12 JAN 2021
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	12 JAN 2021
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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:33:35

Generated On: 09 Jun 2021 17:12:51

Date of Contact	29 AUG 2020
Time of Contact	10:00
Date and Time of Contact (derived)	29 AUG 2020 10:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Symptom Day

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	37 C	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	30 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.9 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

363 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	31 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	1 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	2 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	3 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	4 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Day 33	<input type="checkbox"/>
	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	5 SEP 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.1 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 2694

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	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"/>

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:33:16

Generated On: 09 Jun 2021 17:12:51

Date of Visit	29 AUG 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	29 AUG 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

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Apr 2021 00:33:35

Generated On: 09 Jun 2021 17:12:51

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	31 AUG 2020
Day 5	Yes	02 SEP 2020
Day 7	Yes	04 SEP 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 JAN 2021
Day 5	Yes	16 JAN 2021
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 11:00
Height (xxx.x)	181.0 cm
Weight (xxx.x)	108.7 kg
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362210

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

US3362210

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 AUG 2020

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	12:50 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 12:50
Height (<i>xxx.x</i>)	181 cm
Weight (<i>xxx.x</i>)	108.7 kg
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362210

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3362210

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 JAN 2021

US3362210

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

Visit date (dd MMM yyyy)	25 JAN 2021
--------------------------	-------------

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

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

US3362210

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3362210

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

07:19 (24 HR)

Collection date and time (derived)

25 JAN 2021 07:19

US3362210

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:33:36

Generated On: 09 Jun 2021 17:12:51

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

Collection date (dd MMM yyyy)	25 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	07:51
---------------------------------	-------

Collection Date and Time (derived)	25 JAN 2021 07:51
------------------------------------	-------------------

US3362210

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:18:08

Generated On: 09 Jun 2021 17:12:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Mar 2021 00:10:03

Generated On: 09 Jun 2021 17:12:51

AEID

Adverse event

UPPER RESPIRATORY ILLNESS

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)

22 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

407 of 2694

EAB) (1725)

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Mar 2021 00:10:03

Generated On: 09 Jun 2021 17:12:51

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Mar 2021 00:10:03

Generated On: 09 Jun 2021 17:12:51

AEID	USA-US112-2021-MRNA-1273-P30 1000005
Adverse event	PNEUMONIA RIGHT LOWER LOBE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	9 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	409 of 2694

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Mar 2021 00:10:03

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Mar 2021 00:10:03

Generated On: 09 Jun 2021 17:12:51

PRESENTED TO HOSPITAL FOR
SHORTNESS OF BREATH,
FEVER, NAUSEA, AND
VOMITING. FOUND TO BE
HYPOXIC AT 87% AND PLACED
ON 2L NC, FEBRILE TO 101.7.
SEPSIS WORKUP STARTED AND
FOUND RIGHT SIDED
PNEUMONIA. NO WHITE
COUNT. RAPID COVID
NEGATIVE. GIVEN
CEFTRIAXONE AND
AZITHROMYCIN AS WELL AS 30
CC/KG FLUID BOLUS.

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

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Mar 2021 00:10:03

Generated On: 09 Jun 2021 17:12:51

AEID

Adverse event

ASTHMA EXACERBATION

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)

08 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

412 of 2694

EAB) (1725)

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Mar 2021 00:10:03

Generated On: 09 Jun 2021 17:12:51

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:56:21

Generated On: 09 Jun 2021 17:12:51

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

Yes ☒

No ☐

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

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication FLUTICASONE PROPIONATE
SALMETEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 250/50/1

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

If dose unit is Other, specify MCG/PUFF

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

415 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

417 of 2694

EAB) (1725)

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication ALBUTEROL HFA

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

419 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2.5/3

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

421 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

423 of 2694

EAB) (1725)

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD (ACID REFLUX)

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

425 of 2694

EAB) (1725)

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY ILLNESS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

427 of 2694

EAB) (1725)

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication GUAIFENESIN/DEXTROMETHORPHAN HYDROBROMIDE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 600/30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

429 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

431 of 2694

EAB) (1725)

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication BENZONATATE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

433 of 2694

EAB) (1725)

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication ALBUTEROL/IPRATROPIUM

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA/ASTHMA
EXACERBATION

Dose per administration 2.5/0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

435 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	14 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA RIGHT LOWER LOBE

Dose per administration 3063

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

437 of 2694

EAB) (1725)

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication CEFTRAIXONE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA RIGHT LOWER LOBE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

439 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA RIGHT LOWER LOBE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

441 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

Name of Medication	OXYGEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PNEUMONIA RIGHT LOWER LOBE
Dose per administration	2
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	LITERS/MIN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

443 of 2694

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 00:56:19

Generated On: 09 Jun 2021 17:12:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:56:21

Generated On: 09 Jun 2021 17:12:51

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3362210

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:12:51

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

US3362210

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:12:51

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 ☐

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

SAEID	USA-US112-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

SAEID	USA-US112-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/JAN/2021 13:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

SAEID	USA-US112-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/JAN/2021 13:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

SAEID	USA-US112-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/JAN/2021 19:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 00:33:37

Generated On: 09 Jun 2021 17:12:51

SAEID	USA-US112-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	04/FEB/2021 10:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3362210 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362210

Form: Participant Creation

Generated On: 09 Jun 2021 17:12:51

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User entered 'US3362210'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:41

US3362210

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:03:05

US3362210

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:42

US3362210

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:03:05

US3362210

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'SCRN'	System	21 Aug 2020 14:03:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:44

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '52'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'YEARS'	System	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '52'	System	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:04:05

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Aug 2020'	System	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2020'	System	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 14:04:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 14:04:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:04:34
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:04:27
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:04:27

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:42

US3362210

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'I'	System	21 Aug 2020 14:04:40

US3362210

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:04:40

US3362210

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:12:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:46:54

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User closed query 'Per DM CLR: Please specify the type (low-grade, high-grade) of BARRETT'S ESOPHAGUS DYSPLASIA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:34:50
Query 'Per DM CLR: Please specify the type (low-grade, high-grade) of BARRETT'S ESOPHAGUS DYSPLASIA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UNKNOWN' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:21:57
User opened query 'Per DM CLR: Please specify the type (low-grade, high-grade) of BARRETT'S ESOPHAGUS DYSPLASIA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 03:56:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's esophagus high grade dysplasia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:47:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:47:20
Data point term sent to Coder	System	21 Aug 2020 19:21:06
User entered 'barrett's esophagus dysplasia'	(b) (4), (b) (6)	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '21 Sep 2018'	(b) (4), (b) (6)	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Sep 2018'	System	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2018'	System	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered empty.	System	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered empty.	System	21 Aug 2020 19:20:46

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:23:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:23:19
Data point term sent to Coder	System	21 Aug 2020 19:22:08
User entered 'asthma'	(b) (4), (b) (6)	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'un UNK 1969'	(b) (4), (b) (6)	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 1969'	System	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '1969'	System	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered empty.	System	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered empty.	System	21 Aug 2020 19:21:12

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:23:17
Data point term sent to Coder	System	21 Aug 2020 19:22:10
User entered 'hyperlipidemia'	(b) (4), (b) (6)	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '14 Jun 2019'	(b) (4), (b) (6)	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jun 2019'	System	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2019'	System	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered empty.	System	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered empty.	System	21 Aug 2020 19:21:35

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 05:19:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 05:19:25
Data point term sent to Coder	System	21 Aug 2020 19:23:15
User entered 'Right foot fracture'	(b) (4), (b) (6)	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 2019'	System	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2019'	System	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 2019'	System	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2019'	System	21 Aug 2020 19:22:32

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Foot infection - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 05:12:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 05:12:30
Data point term sent to Coder	System	21 Aug 2020 19:23:16
User entered 'right foot infection'	(b) (4), (b) (6)	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 2019'	System	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2019'	System	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 2019'	System	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2019'	System	21 Aug 2020 19:23:05

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin grafts, PT: Skin graft, LLT: Skin graft - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:49
Data point term sent to Coder	System	24 Aug 2020 20:28:15
User entered 'RIGHT FOOT SKIN GRAFT' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:27:31
Data point term sent to Coder	System	21 Aug 2020 19:24:20
User entered 'right foot skin grate'	(b) (4), (b) (6)	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 2019'	System	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2019'	System	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 2019'	System	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2019'	System	21 Aug 2020 19:23:35

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:25:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:25:42
Data point term sent to Coder	System	29 Sep 2020 18:24:22
User entered 'GERD (ACID REFLUX)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 18:24:11
Data point term sent to Coder	System	29 Sep 2020 18:23:21
User entered 'GERD'	(b) (4), (b) (6)	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'UN UNK 2015'	(b) (4), (b) (6)	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:09:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:09:17
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Jan 2015'	System	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2015'	System	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'Sep 2020'	System	16 Nov 2020 21:09:17
User entered empty.	System	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '2020'	System	16 Nov 2020 21:09:17
User entered empty.	System	29 Sep 2020 18:22:39

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User closed query 'Per CDM: Please confirm if time 07:55 is AM or PM. Thank you!' (Site from DM).	(b) (4)	
Query 'Per CDM: Please confirm if time 07:55 is AM or PM. Thank you!' answered with 'AM' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:41:53
Query 'Per CDM: Please confirm if time 07:55 is AM or PM. Thank you!' answered with 'AM' (Site from DM).	Amy Thomassie (b) (4)	26 Sep 2020 00:45:03
User opened query 'Per CDM: Please confirm if time 07:55 is AM or PM. Thank you!' (Site from DM).	(b) (4)	
User entered '07:55'	(b) (4), (b) (6)	25 Sep 2020 11:09:34
	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered '21 Aug 2020 07:55'	System	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '181' cm	(b) (4), (b) (6)	21 Aug 2020 19:24:48
DataPoint set to visible.	System	21 Aug 2020 14:04:40

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '108.7' kg	(b) (4), (b) (6)	21 Aug 2020 19:24:48
DataPoint set to visible.	System	21 Aug 2020 14:04:40

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
Amendment Manager: User entered '33.17970'	System	17 Sep 2020 00:17:39
User entered '33.2'	System	21 Aug 2020 19:24:48
DataPoint set to visible.	System	21 Aug 2020 14:04:40

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'kg/m2'	System	21 Aug 2020 19:24:48
DataPoint set to visible.	System	21 Aug 2020 14:04:40

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:41:54
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:45:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:45:41
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:09:24
User entered '36.9' C	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	26 Sep 2020 00:45:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 00:45:41
User entered '73'	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'bpm'	System	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 00:45:41
User entered '18'	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'breaths/min'	System	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 00:45:41
User entered '126'	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'mmHg'	System	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 00:45:41
User entered '86'	(b) (4), (b) (6)	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User entered 'mmHg'	System	21 Aug 2020 19:24:48

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04

US3362210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04

US3362210

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:24:59

US3362210

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 19:24:59

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'facility maintenance manager fro (b) (6) store throughout LA, and MS.'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:13:04
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:22:41
User entered 'Nephew is EKG tech (b) (6) spouse stays at home'	(b) (4), (b) (6)	21 Aug 2020 19:27:23

US3362210

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	21 Aug 2020 13:42:19

US3362210

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	21 Aug 2020 13:42:19

US3362210

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	21 Aug 2020 13:42:19

US3362210

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'VISIT1'	System	21 Aug 2020 13:42:19

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:39:40

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '144582'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:39:40

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:39:40

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:28:02

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:28:02

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:28:02

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:28:02

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:28:02

US3362210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:03:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:55:39

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 07:23:03
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:44:36
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:09:09
User entered '181' cm	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 00:44:36
User entered '108.7' kg	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 07:23:03
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:44:36
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:09:09
User entered '181' cm	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 00:44:36
User entered '108.7' kg	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '07:55'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered '21 Aug 2020 07:55'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '36.9' C	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '73'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'bpm'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '18'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'breaths/min'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '126'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'mmHg'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '86'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'mmHg'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 07:23:03
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 00:44:36
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:09:09
User entered '181' cm	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 00:44:36
User entered '108.7' kg	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '09:38'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered '21 Aug 2020 09:38'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '37.0' C	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '67'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'bpm'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '18'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'breaths/min'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '122'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'mmHg'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '76'	(b) (4), (b) (6)	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'mmHg'	System	21 Aug 2020 20:37:55

US3362210

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:38:38

US3362210

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:38:38

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '09:01'	(b) (4), (b) (6)	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered '21 Aug 2020 09:01'	System	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'ONCE'	System	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 14:05:24

US3362210

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:40:02

US3362210

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:40:02

US3362210

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '08:32'	(b) (4), (b) (6)	21 Aug 2020 20:40:02

US3362210

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered '21 Aug 2020 08:32'	System	21 Aug 2020 20:40:02

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '08:30'	(b) (4), (b) (6)	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered '21 Aug 2020 08:30'	System	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered empty.	System	21 Aug 2020 20:40:27

US3362210

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:40:41

US3362210

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'I'	System	21 Aug 2020 20:40:41

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:33:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '413d8f39-81d3-4db1-aa9e-99c70c479d96' User entered 'Yes (Y)'	System	21 Aug 2020 14:35:41
	System	21 Aug 2020 14:35:41

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:33:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '413d8f39-81d3-4db1-aa9e-99c70c479d96' User entered '98.6'	System	21 Aug 2020 14:35:41
	System	21 Aug 2020 14:35:41

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:33:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '413d8f39-81d3-4db1-aa9e-99c70c479d96'	System	21 Aug 2020 14:35:41
User entered 'No (N)'	System	21 Aug 2020 14:35:41

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:35:39', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '413d8f39-81d3-4db1-aa9e-99c70c479d96'	System	21 Aug 2020 14:35:41
User entered '21 Aug 2020 09:35'	System	21 Aug 2020 14:35:41

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 09:21'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 11:51'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:03:39', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '11f6858b-253c-4278-9542-1b4a02665841' User entered 'Yes (Y)'	System	22 Aug 2020 00:06:10
	System	22 Aug 2020 00:06:10

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:05:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '11f6858b-253c-4278-9542-1b4a02665841' User entered '100.4'	System	22 Aug 2020 00:06:10
	System	22 Aug 2020 00:06:10

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:06:02', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '11f6858b-253c-4278-9542-1b4a02665841'	System	22 Aug 2020 00:06:10
User entered 'No (N)'	System	22 Aug 2020 00:06:10

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:06:07', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '11f6858b-253c-4278-9542-1b4a02665841' User entered '21 Aug 2020 19:06'	System	22 Aug 2020 00:06:10
	System	22 Aug 2020 00:06:10

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 12:46'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 2'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:02:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '126d9862-57af-4584-8c7a-ba22d30db0e0' User entered 'Yes (Y)'	System	23 Aug 2020 00:02:45
	System	23 Aug 2020 00:02:45

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:02:33', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '126d9862-57af-4584-8c7a-ba22d30db0e0' User entered '100.5'	System	23 Aug 2020 00:02:45
	System	23 Aug 2020 00:02:45

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:02:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '126d9862-57af-4584-8c7a-ba22d30db0e0'	System	23 Aug 2020 00:02:45
User entered 'No (N)'	System	23 Aug 2020 00:02:45

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:02:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '126d9862-57af-4584-8c7a-ba22d30db0e0'	System	23 Aug 2020 00:02:45
User entered '22 Aug 2020 19:02'	System	23 Aug 2020 00:02:45

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 3'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:51:44', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b0014a43-e68b-4d60-b867-4ffb14289b27' User entered 'Yes (Y)'	System	23 Aug 2020 23:52:00
	System	23 Aug 2020 23:52:00

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:51:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b0014a43-e68b-4d60-b867-4ffb14289b27' User entered '99.9'	System	23 Aug 2020 23:52:00
	System	23 Aug 2020 23:52:00

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:51:52', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b0014a43-e68b-4d60-b867-4ffb14289b27'	System	23 Aug 2020 23:52:00
User entered 'No (N)'	System	23 Aug 2020 23:52:00

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:51:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b0014a43-e68b-4d60-b867-4ffb14289b27' User entered '23 Aug 2020 18:51'	System	23 Aug 2020 23:52:00
	System	23 Aug 2020 23:52:00

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 4'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:16', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c782677a-ae07-4e5f-9a47-4a39a10a59d2' User entered 'Yes (Y)'	System	25 Aug 2020 00:18:30
	System	25 Aug 2020 00:18:30

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:21', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c782677a-ae07-4e5f-9a47-4a39a10a59d2' User entered '100.4'	System	25 Aug 2020 00:18:30
	System	25 Aug 2020 00:18:30

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c782677a-ae07-4e5f-9a47-4a39a10a59d2'	System	25 Aug 2020 00:18:30
User entered 'No (N)'	System	25 Aug 2020 00:18:30

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c782677a-ae07-4e5f-9a47-4a39a10a59d2' User entered '24 Aug 2020 19:18'	System	25 Aug 2020 00:18:30
	System	25 Aug 2020 00:18:30

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 5'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '924be285-f32b-4c49-829e-a175dc4a99b6' User entered 'Yes (Y)'	System	25 Aug 2020 23:52:46
	System	25 Aug 2020 23:52:46

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:36', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '924be285-f32b-4c49-829e-a175dc4a99b6' User entered '99.5'	System	25 Aug 2020 23:52:46
	System	25 Aug 2020 23:52:46

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:39', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '924be285-f32b-4c49-829e-a175dc4a99b6'	System	25 Aug 2020 23:52:46
User entered 'No (N)'	System	25 Aug 2020 23:52:46

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:44', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '924be285-f32b-4c49-829e-a175dc4a99b6' User entered '25 Aug 2020 18:52'	System	25 Aug 2020 23:52:46
	System	25 Aug 2020 23:52:46

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 6'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:58:44', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0779eeb2-3181-42b6-a277-772b2863db79' User entered 'Yes (Y)'	System	26 Aug 2020 23:59:02
	System	26 Aug 2020 23:59:02

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:58:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0779eeb2-3181-42b6-a277-772b2863db79' User entered '98.7'	System	26 Aug 2020 23:59:02
	System	26 Aug 2020 23:59:02

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:58:54', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0779eeb2-3181-42b6-a277-772b2863db79'	System	26 Aug 2020 23:59:02
User entered 'No (N)'	System	26 Aug 2020 23:59:02

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0779eeb2-3181-42b6-a277-772b2863db79' User entered '26 Aug 2020 18:59'	System	26 Aug 2020 23:59:02
	System	26 Aug 2020 23:59:02

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 7'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:49:47', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db741707-c175-40ff-a82c-439c7e788804'	System	27 Aug 2020 23:50:04
User entered 'Yes (Y)'	System	27 Aug 2020 23:50:04

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:49:53', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db741707-c175-40ff-a82c-439c7e788804' User entered '99.5'	System	27 Aug 2020 23:50:04
	System	27 Aug 2020 23:50:04

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:49:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db741707-c175-40ff-a82c-439c7e788804'	System	27 Aug 2020 23:50:04
User entered 'No (N)'	System	27 Aug 2020 23:50:04

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db741707-c175-40ff-a82c-439c7e788804'	System	27 Aug 2020 23:50:04
User entered '27 Aug 2020 18:50'	System	27 Aug 2020 23:50:04

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:35:54', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8353877a-f825-4af1-be2e-91bc30d42f06'	System	21 Aug 2020 14:36:22
User entered 'None (1)'	System	21 Aug 2020 14:36:22

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:35:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8353877a-f825-4af1-be2e-91bc30d42f06'	System	21 Aug 2020 14:36:22
User entered 'No (N)'	System	21 Aug 2020 14:36:22

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:36:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8353877a-f825-4af1-be2e-91bc30d42f06'	System	21 Aug 2020 14:36:22
User entered 'No (N)'	System	21 Aug 2020 14:36:22

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:36:17', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8353877a-f825-4af1-be2e-91bc30d42f06'	System	21 Aug 2020 14:36:22
User entered 'None (1)'	System	21 Aug 2020 14:36:22

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:36:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8353877a-f825-4af1-be2e-91bc30d42f06' User entered '21 Aug 2020 09:36'	System	21 Aug 2020 14:36:22
	System	21 Aug 2020 14:36:22

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 09:21'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 11:51'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:06:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f706a90f-0a09-4928-9fad-bcb4f693b4af'	System	22 Aug 2020 00:07:35
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 00:07:35

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:07:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f706a90f-0a09-4928-9fad-bcb4f693b4af'	System	22 Aug 2020 00:07:35
User entered 'No (N)'	System	22 Aug 2020 00:07:35

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:07:08', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f706a90f-0a09-4928-9fad-bcb4f693b4af' User entered 'No (N)'	System	22 Aug 2020 00:07:35
	System	22 Aug 2020 00:07:35

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:07:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f706a90f-0a09-4928-9fad-bcb4f693b4af' User entered 'None (1)'	System	22 Aug 2020 00:07:35
	System	22 Aug 2020 00:07:35

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:07:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f706a90f-0a09-4928-9fad-bcb4f693b4af' User entered '21 Aug 2020 19:07'	System	22 Aug 2020 00:07:35
	System	22 Aug 2020 00:07:35

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 12:46'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 2'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:03:03', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '43f25031-dce7-4be0-b426-8356c73fc1b2'	System	23 Aug 2020 00:03:47
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 00:03:47

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:03:14', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '43f25031-dce7-4be0-b426-8356c73fc1b2'	System	23 Aug 2020 00:03:47
User entered 'No (N)'	System	23 Aug 2020 00:03:47

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:03:27', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '43f25031-dce7-4be0-b426-8356c73fc1b2' User entered 'No (N)'	System	23 Aug 2020 00:03:47
	System	23 Aug 2020 00:03:47

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:03:41', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '43f25031-dce7-4be0-b426-8356c73fc1b2'	System	23 Aug 2020 00:03:47
User entered 'None (1)'	System	23 Aug 2020 00:03:47

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:03:46', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '43f25031-dce7-4be0-b426-8356c73fc1b2' User entered '22 Aug 2020 19:03'	System	23 Aug 2020 00:03:47
	System	23 Aug 2020 00:03:47

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 3'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:01', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '096f2bc6-5dca-4469-9bde-69a1d7d61bd8'	System	23 Aug 2020 23:52:15
User entered 'None (1)'	System	23 Aug 2020 23:52:15

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:04', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '096f2bc6-5dca-4469-9bde-69a1d7d61bd8' User entered 'No (N)'	System	23 Aug 2020 23:52:15
	System	23 Aug 2020 23:52:15

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:06', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '096f2bc6-5dca-4469-9bde-69a1d7d61bd8' User entered 'No (N)'	System	23 Aug 2020 23:52:15
	System	23 Aug 2020 23:52:15

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:09', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '096f2bc6-5dca-4469-9bde-69a1d7d61bd8' User entered 'None (1)'	System	23 Aug 2020 23:52:15
	System	23 Aug 2020 23:52:15

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:12', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '096f2bc6-5dca-4469-9bde-69a1d7d61bd8' User entered '23 Aug 2020 18:52'	System	23 Aug 2020 23:52:15
	System	23 Aug 2020 23:52:15

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 4'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59955c44-871e-43d2-bd5c-b24b67dad024'	System	25 Aug 2020 00:18:52
User entered 'None (1)'	System	25 Aug 2020 00:18:52

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:35', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59955c44-871e-43d2-bd5c-b24b67dad024'	System	25 Aug 2020 00:18:52
User entered 'No (N)'	System	25 Aug 2020 00:18:52

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59955c44-871e-43d2-bd5c-b24b67dad024'	System	25 Aug 2020 00:18:52
User entered 'No (N)'	System	25 Aug 2020 00:18:52

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:46', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59955c44-871e-43d2-bd5c-b24b67dad024'	System	25 Aug 2020 00:18:52
User entered 'None (1)'	System	25 Aug 2020 00:18:52

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59955c44-871e-43d2-bd5c-b24b67dad024' User entered '24 Aug 2020 19:18'	System	25 Aug 2020 00:18:52
	System	25 Aug 2020 00:18:52

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 5'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0ffcd13e-2bfc-4f9d-a23f-ee5f99f67062'	System	25 Aug 2020 23:53:05
User entered 'None (1)'	System	25 Aug 2020 23:53:05

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:51', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0ffcd13e-2bfc-4f9d-a23f-ee5f99f67062'	System	25 Aug 2020 23:53:05
User entered 'No (N)'	System	25 Aug 2020 23:53:05

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:54', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0ffcd13e-2bfc-4f9d-a23f-ee5f99f67062'	System	25 Aug 2020 23:53:05
User entered 'No (N)'	System	25 Aug 2020 23:53:05

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:52:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0ffcd13e-2bfc-4f9d-a23f-ee5f99f67062'	System	25 Aug 2020 23:53:05
User entered 'None (1)'	System	25 Aug 2020 23:53:05

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:02', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0ffcd13e-2bfc-4f9d-a23f-ee5f99f67062'	System	25 Aug 2020 23:53:05
User entered '25 Aug 2020 18:53'	System	25 Aug 2020 23:53:05

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 6'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:04', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f322cc85-6eb0-4cf3-a9bc-8ca55a837ad4'	System	26 Aug 2020 23:59:19
User entered 'None (1)'	System	26 Aug 2020 23:59:19

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:08', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f322cc85-6eb0-4cf3-a9bc-8ca55a837ad4'	System	26 Aug 2020 23:59:19
User entered 'No (N)'	System	26 Aug 2020 23:59:19

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:11', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f322cc85-6eb0-4cf3-a9bc-8ca55a837ad4'	System	26 Aug 2020 23:59:19
User entered 'No (N)'	System	26 Aug 2020 23:59:19

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:14', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f322cc85-6eb0-4cf3-a9bc-8ca55a837ad4'	System	26 Aug 2020 23:59:19
User entered 'None (1)'	System	26 Aug 2020 23:59:19

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:17', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f322cc85-6eb0-4cf3-a9bc-8ca55a837ad4'	System	26 Aug 2020 23:59:19
User entered '26 Aug 2020 18:59'	System	26 Aug 2020 23:59:19

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 7'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:03', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '76a3aaaf-b879-4e87-86bc-f16d2fcbee88'	System	27 Aug 2020 23:50:16
User entered 'None (1)'	System	27 Aug 2020 23:50:16

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:06', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '76a3aaaf-b879-4e87-86bc-f16d2fcbee88'	System	27 Aug 2020 23:50:16
User entered 'No (N)'	System	27 Aug 2020 23:50:16

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:09', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '76a3aaaf-b879-4e87-86bc-f16d2fcbee88'	System	27 Aug 2020 23:50:16
User entered 'No (N)'	System	27 Aug 2020 23:50:16

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:11', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '76a3aaaf-b879-4e87-86bc-f16d2fcbee88'	System	27 Aug 2020 23:50:16
User entered 'None (1)'	System	27 Aug 2020 23:50:16

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:13', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '76a3aaaf-b879-4e87-86bc-f16d2fcbee88'	System	27 Aug 2020 23:50:16
User entered '27 Aug 2020 18:50'	System	27 Aug 2020 23:50:16

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:42', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered 'None (0)'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:01', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered 'None (0)'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:05', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered 'None (0)'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:14', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered 'None (0)'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:19', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered 'None (0)'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:23', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered 'None (0)'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered 'No (N)'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T09:37:47', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8fc0fe0a-f303-4aba-a2b9-83aa2ea70f59'	System	21 Aug 2020 14:37:50
User entered '21 Aug 2020 09:37'	System	21 Aug 2020 14:37:50

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 09:21'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 11:51'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:07:44', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered 'None (0)'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:07:51', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered 'None (0)'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:07:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered 'None (0)'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:08:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered 'None (0)'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:08:10', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered 'None (0)'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:08:13', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered 'None (0)'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:08:22', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered 'No (N)'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-21T19:08:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '47c69397-1f8e-410a-843b-f7e42d0795fa' User entered '21 Aug 2020 19:08'	System	22 Aug 2020 00:08:30
	System	22 Aug 2020 00:08:30

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '21 Aug 2020 12:46'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 2'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:03:53', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered 'None (0)'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:04:02', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered 'None (0)'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:04:07', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered 'None (0)'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:04:11', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered 'None (0)'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:04:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered 'None (0)'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:04:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered 'None (0)'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:04:38', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered 'No (N)'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-22T19:04:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'e5f8722b-feef-4866-b7da-1593b4c52e4a' User entered '22 Aug 2020 19:04'	System	23 Aug 2020 00:04:45
	System	23 Aug 2020 00:04:45

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 3'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered 'None (0)'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:21', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered 'None (0)'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered 'None (0)'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:27', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered 'None (0)'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered 'None (0)'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered 'None (0)'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:36', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered 'No (N)'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-23T18:52:40', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3bca3fcc-ece1-413f-bd9a-4b4aed8ebbb1' User entered '23 Aug 2020 18:52'	System	23 Aug 2020 23:52:41
	System	23 Aug 2020 23:52:41

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 4'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:53', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered 'None (0)'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered 'None (0)'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered 'None (0)'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:18:59', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered 'None (0)'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:19:04', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered 'None (0)'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:19:06', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered 'None (0)'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:19:09', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered 'No (N)'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-24T19:19:14', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '97f29f57-fa4c-4c04-8f9d-39d365f97c9a' User entered '24 Aug 2020 19:19'	System	25 Aug 2020 00:19:16
	System	25 Aug 2020 00:19:16

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 5'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:11', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered 'None (0)'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:16', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered 'None (0)'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered 'None (0)'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:22', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered 'None (0)'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered 'None (0)'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:27', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered 'None (0)'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:31', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered 'No (N)'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-25T18:53:35', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63dd6f6d-4da8-4456-9820-689c56cace18' User entered '25 Aug 2020 18:53'	System	25 Aug 2020 23:53:38
	System	25 Aug 2020 23:53:38

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 6'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:22', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered 'None (0)'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered 'None (0)'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:27', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered 'None (0)'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered 'None (0)'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered 'None (0)'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:39', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered 'None (0)'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered 'No (N)'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-26T18:59:48', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '956e6f36-3407-4891-a9a9-3d33734a1ed6' User entered '26 Aug 2020 18:59'	System	26 Aug 2020 23:59:52
	System	26 Aug 2020 23:59:52

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 7'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered 'None (0)'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered 'None (0)'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:21', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered 'None (0)'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered 'None (0)'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:26', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered 'None (0)'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered 'None (0)'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered 'No (N)'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-08-27T18:50:33', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fbb914c-6c79-45cf-9eed-0732258fb04e' User entered '27 Aug 2020 18:50'	System	27 Aug 2020 23:50:37
	System	27 Aug 2020 23:50:37

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 14:05:24

US3362210

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	28 Aug 2020 21:46:11

US3362210

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '28 Aug 2020'	Crystal Rowell (b) (4)	28 Aug 2020 21:46:11

US3362210

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	28 Aug 2020 21:46:11

US3362210

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	Crystal Rowell (b) (4)	28 Aug 2020 21:46:11

US3362210

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	28 Aug 2020 21:46:27

US3362210

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'I'	System	28 Aug 2020 21:46:27

US3362210

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	11 Sep 2020 14:23:12
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Sep 2020 14:22:22
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	11 Sep 2020 14:22:22
	(b) (4)	

US3362210

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '4 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Sep 2020 14:23:12
User entered empty.	Crystal Rowell (b) (4)	11 Sep 2020 14:22:22

US3362210

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Sep 2020 14:22:34
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Crystal Rowell (b) (4)	11 Sep 2020 14:22:22
	(b) (4)	

US3362210

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Pt was in convalescent period safety call time frame during safety day 15'	Crystal Rowell (b) (4)	11 Sep 2020 14:22:22

US3362210

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	11 Sep 2020 14:23:21

US3362210

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:27
User entered 'I'	System	11 Sep 2020 14:23:21

US3362210

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	11 Sep 2020 14:23:31

US3362210

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '11 Sep 2020'	Crystal Rowell (b) (4)	11 Sep 2020 14:23:31

US3362210

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	11 Sep 2020 14:23:31

US3362210

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	Crystal Rowell (b) (4)	11 Sep 2020 14:23:31

US3362210

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	11 Sep 2020 14:23:35

US3362210

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'I'	System	11 Sep 2020 14:23:35

US3362210

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:13

US3362210

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:13

US3362210

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:13

US3362210

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'VISIT2'	System	30 Sep 2020 15:20:13

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '10:00'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '22 Sep 2020 10:00'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '37.4' C	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '66'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'bpm'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '18'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'breaths/min'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '134'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'mmHg'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '94'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'mmHg'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '11:20'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '22 Sep 2020 11:20'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '36.8' C	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '62'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'bpm'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '18'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'breaths/min'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '131'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'mmHg'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '73'	(b) (4), (b) (6)	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'mmHg'	System	22 Sep 2020 17:46:54

US3362210

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 17:14:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 17:14:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 17:14:11
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:20:24
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:20:24

US3362210

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:24

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	22 Sep 2020 16:19:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 08:47:14
Query 'Data is required. Please complete.' answered with 'Day 29 is not due until after 18Sep2020' (Site from System).	Amy Thomassie (b) (4)	15 Sep 2020 16:18:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Sep 2020 13:48:04
	(b) (4), (b) (6)	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 16:19:10
User entered empty.	System	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '22 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 16:19:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '10:47' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 16:19:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '22 Sep 2020 10:47'	System	22 Sep 2020 16:19:10
User entered empty.	System	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Right Arm (RIGHT ARM)' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 16:19:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'ONCE'	System	22 Sep 2020 16:19:10
User entered empty.	System	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 16:19:10
User entered empty.	System	14 Sep 2020 13:48:04

US3362210

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:22

US3362210

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:22

US3362210

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '10:16' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 15:21:45
User entered '10:00'	(b) (4), (b) (6)	30 Sep 2020 15:21:22

US3362210

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '22 Sep 2020 10:16'	System	30 Sep 2020 15:21:45
User entered '22 Sep 2020 10:00'	System	30 Sep 2020 15:21:22

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '22 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '10:14'	(b) (4), (b) (6)	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '22 Sep 2020 10:14'	System	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered empty.	System	30 Sep 2020 15:22:14

US3362210

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:41

US3362210

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '1'	System	30 Sep 2020 15:18:41

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:08', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f018f8b8-2c19-4422-aae7-998a0513543d' User entered 'Yes (Y)'	System	22 Sep 2020 16:21:23
	System	22 Sep 2020 16:21:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:13', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f018f8b8-2c19-4422-aae7-998a0513543d' User entered '98.3'	System	22 Sep 2020 16:21:23
	System	22 Sep 2020 16:21:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f018f8b8-2c19-4422-aae7-998a0513543d' User entered 'No (N)'	System	22 Sep 2020 16:21:23
	System	22 Sep 2020 16:21:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:21', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f018f8b8-2c19-4422-aae7-998a0513543d' User entered '22 Sep 2020 11:21'	System	22 Sep 2020 16:21:23
	System	22 Sep 2020 16:21:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 11:07'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 13:37'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:21:48', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3220a13d-1356-4521-a79b-178cf3797790' User entered 'Yes (Y)'	System	22 Sep 2020 23:22:02
	System	22 Sep 2020 23:22:02

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:21:53', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3220a13d-1356-4521-a79b-178cf3797790' User entered '99.2'	System	22 Sep 2020 23:22:02
	System	22 Sep 2020 23:22:02

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:21:56', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3220a13d-1356-4521-a79b-178cf3797790' User entered 'No (N)'	System	22 Sep 2020 23:22:02
	System	22 Sep 2020 23:22:02

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:21:59', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3220a13d-1356-4521-a79b-178cf3797790' User entered '22 Sep 2020 18:21'	System	22 Sep 2020 23:22:02
	System	22 Sep 2020 23:22:02

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 14:32'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 2'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:32:52', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db3c4196-35c6-4c15-a2ff-28b8cce3042d' User entered 'Yes (Y)'	System	24 Sep 2020 01:33:11
	System	24 Sep 2020 01:33:11

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:32:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db3c4196-35c6-4c15-a2ff-28b8cce3042d' User entered '99.2'	System	24 Sep 2020 01:33:11
	System	24 Sep 2020 01:33:11

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:06', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db3c4196-35c6-4c15-a2ff-28b8cce3042d' User entered 'No (N)'	System	24 Sep 2020 01:33:11
	System	24 Sep 2020 01:33:11

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:09', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'db3c4196-35c6-4c15-a2ff-28b8cce3042d' User entered '23 Sep 2020 18:33'	System	24 Sep 2020 01:33:11
	System	24 Sep 2020 01:33:11

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 3'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:03:59', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '08d8aee4-729c-440f-9bf2-c08e542914c8' User entered 'Yes (Y)'	System	24 Sep 2020 22:04:12
	System	24 Sep 2020 22:04:12

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:03', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '08d8aee4-729c-440f-9bf2-c08e542914c8' User entered '98.9'	System	24 Sep 2020 22:04:12
	System	24 Sep 2020 22:04:12

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:06', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '08d8aee4-729c-440f-9bf2-c08e542914c8' User entered 'No (N)'	System	24 Sep 2020 22:04:12
	System	24 Sep 2020 22:04:12

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:10', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '08d8aee4-729c-440f-9bf2-c08e542914c8' User entered '24 Sep 2020 15:04'	System	24 Sep 2020 22:04:12
	System	24 Sep 2020 22:04:12

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 4'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:13', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8135d387-44ca-4b8f-9120-db7b64ac4de0' User entered 'Yes (Y)'	System	26 Sep 2020 01:41:29
	System	26 Sep 2020 01:41:29

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8135d387-44ca-4b8f-9120-db7b64ac4de0' User entered '99.1'	System	26 Sep 2020 01:41:29
	System	26 Sep 2020 01:41:29

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:23', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8135d387-44ca-4b8f-9120-db7b64ac4de0' User entered 'No (N)'	System	26 Sep 2020 01:41:29
	System	26 Sep 2020 01:41:29

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:26', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8135d387-44ca-4b8f-9120-db7b64ac4de0' User entered '25 Sep 2020 18:41'	System	26 Sep 2020 01:41:29
	System	26 Sep 2020 01:41:29

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 5'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:08', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0b3575d3-c033-4ca9-b28a-214a8c3e7236' User entered 'Yes (Y)'	System	27 Sep 2020 00:27:23
	System	27 Sep 2020 00:27:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:12', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0b3575d3-c033-4ca9-b28a-214a8c3e7236' User entered '98.5'	System	27 Sep 2020 00:27:23
	System	27 Sep 2020 00:27:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:15', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0b3575d3-c033-4ca9-b28a-214a8c3e7236' User entered 'No (N)'	System	27 Sep 2020 00:27:23
	System	27 Sep 2020 00:27:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0b3575d3-c033-4ca9-b28a-214a8c3e7236' User entered '26 Sep 2020 17:27'	System	27 Sep 2020 00:27:23
	System	27 Sep 2020 00:27:23

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 6'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:50:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bdd5331c-2ca0-495d-b727-22f2d4653561' User entered 'Yes (Y)'	System	27 Sep 2020 23:51:21
	System	27 Sep 2020 23:51:21

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:50:58', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bdd5331c-2ca0-495d-b727-22f2d4653561' User entered '99.0'	System	27 Sep 2020 23:51:21
	System	27 Sep 2020 23:51:21

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:10', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bdd5331c-2ca0-495d-b727-22f2d4653561' User entered 'No (N)'	System	27 Sep 2020 23:51:21
	System	27 Sep 2020 23:51:21

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:19', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bdd5331c-2ca0-495d-b727-22f2d4653561' User entered '27 Sep 2020 16:51'	System	27 Sep 2020 23:51:21
	System	27 Sep 2020 23:51:21

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 7'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '4555a539-4619-4635-821a-ef87c3a3f77a' User entered 'Yes (Y)'	System	28 Sep 2020 23:26:30
	System	28 Sep 2020 23:26:30

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:22', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '4555a539-4619-4635-821a-ef87c3a3f77a' User entered '98.8'	System	28 Sep 2020 23:26:30
	System	28 Sep 2020 23:26:30

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '4555a539-4619-4635-821a-ef87c3a3f77a' User entered 'No (N)'	System	28 Sep 2020 23:26:30
	System	28 Sep 2020 23:26:30

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '4555a539-4619-4635-821a-ef87c3a3f77a' User entered '28 Sep 2020 16:26'	System	28 Sep 2020 23:26:30
	System	28 Sep 2020 23:26:30

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:29', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3f17c5dc-2853-4a7a-b4f0-08832db20d64'	System	22 Sep 2020 16:21:53
User entered 'None (1)'	System	22 Sep 2020 16:21:53

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3f17c5dc-2853-4a7a-b4f0-08832db20d64' User entered 'No (N)'	System	22 Sep 2020 16:21:53
	System	22 Sep 2020 16:21:53

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:40', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3f17c5dc-2853-4a7a-b4f0-08832db20d64' User entered 'No (N)'	System	22 Sep 2020 16:21:53
	System	22 Sep 2020 16:21:53

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:47', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3f17c5dc-2853-4a7a-b4f0-08832db20d64' User entered 'None (1)'	System	22 Sep 2020 16:21:53
	System	22 Sep 2020 16:21:53

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '3f17c5dc-2853-4a7a-b4f0-08832db20d64'	System	22 Sep 2020 16:21:53
User entered '22 Sep 2020 11:21'	System	22 Sep 2020 16:21:53

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 11:07'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 13:37'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:05', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '471e92a9-b07d-4700-8fb6-e0e7d724b35b'	System	22 Sep 2020 23:22:30
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 23:22:30

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:13', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '471e92a9-b07d-4700-8fb6-e0e7d724b35b' User entered 'No (N)'	System	22 Sep 2020 23:22:30
	System	22 Sep 2020 23:22:30

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '471e92a9-b07d-4700-8fb6-e0e7d724b35b' User entered 'No (N)'	System	22 Sep 2020 23:22:30
	System	22 Sep 2020 23:22:30

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '471e92a9-b07d-4700-8fb6-e0e7d724b35b' User entered 'None (1)'	System	22 Sep 2020 23:22:30
	System	22 Sep 2020 23:22:30

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '471e92a9-b07d-4700-8fb6-e0e7d724b35b' User entered '22 Sep 2020 18:22'	System	22 Sep 2020 23:22:30
	System	22 Sep 2020 23:22:30

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 14:32'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 2'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:15', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af543f9c-008a-4eea-b352-88aee8c0b4c7' User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 01:33:29
	System	24 Sep 2020 01:33:29

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af543f9c-008a-4eea-b352-88aee8c0b4c7' User entered 'No (N)'	System	24 Sep 2020 01:33:29
	System	24 Sep 2020 01:33:29

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:21', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af543f9c-008a-4eea-b352-88aee8c0b4c7' User entered 'No (N)'	System	24 Sep 2020 01:33:29
	System	24 Sep 2020 01:33:29

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af543f9c-008a-4eea-b352-88aee8c0b4c7'	System	24 Sep 2020 01:33:29
User entered 'None (1)'	System	24 Sep 2020 01:33:29

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:26', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af543f9c-008a-4eea-b352-88aee8c0b4c7' User entered '23 Sep 2020 18:33'	System	24 Sep 2020 01:33:29
	System	24 Sep 2020 01:33:29

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 3'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9f4a690c-a6f0-405c-9e71-4d854ed926f4' User entered 'None (1)'	System	24 Sep 2020 22:04:35
	System	24 Sep 2020 22:04:35

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:21', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9f4a690c-a6f0-405c-9e71-4d854ed926f4' User entered 'No (N)'	System	24 Sep 2020 22:04:35
	System	24 Sep 2020 22:04:35

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9f4a690c-a6f0-405c-9e71-4d854ed926f4' User entered 'No (N)'	System	24 Sep 2020 22:04:35
	System	24 Sep 2020 22:04:35

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:27', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9f4a690c-a6f0-405c-9e71-4d854ed926f4' User entered 'None (1)'	System	24 Sep 2020 22:04:35
	System	24 Sep 2020 22:04:35

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9f4a690c-a6f0-405c-9e71-4d854ed926f4' User entered '24 Sep 2020 15:04'	System	24 Sep 2020 22:04:35
	System	24 Sep 2020 22:04:35

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 4'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f658799f-6b1e-4542-83ac-4a3a415fdb06'	System	26 Sep 2020 01:41:43
User entered 'None (1)'	System	26 Sep 2020 01:41:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f658799f-6b1e-4542-83ac-4a3a415fdb06'	System	26 Sep 2020 01:41:43
User entered 'No (N)'	System	26 Sep 2020 01:41:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:35', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f658799f-6b1e-4542-83ac-4a3a415fdb06'	System	26 Sep 2020 01:41:43
User entered 'No (N)'	System	26 Sep 2020 01:41:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f658799f-6b1e-4542-83ac-4a3a415fdb06'	System	26 Sep 2020 01:41:43
User entered 'None (1)'	System	26 Sep 2020 01:41:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:39', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f658799f-6b1e-4542-83ac-4a3a415fdb06'	System	26 Sep 2020 01:41:43
User entered '25 Sep 2020 18:41'	System	26 Sep 2020 01:41:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 5'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:25', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '58988037-1664-4488-a2b8-ac6704b85c28'	System	27 Sep 2020 00:27:38
User entered 'None (1)'	System	27 Sep 2020 00:27:38

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '58988037-1664-4488-a2b8-ac6704b85c28'	System	27 Sep 2020 00:27:38
User entered 'No (N)'	System	27 Sep 2020 00:27:38

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:31', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '58988037-1664-4488-a2b8-ac6704b85c28'	System	27 Sep 2020 00:27:38
User entered 'No (N)'	System	27 Sep 2020 00:27:38

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:33', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '58988037-1664-4488-a2b8-ac6704b85c28'	System	27 Sep 2020 00:27:38
User entered 'None (1)'	System	27 Sep 2020 00:27:38

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:36', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '58988037-1664-4488-a2b8-ac6704b85c28'	System	27 Sep 2020 00:27:38
User entered '26 Sep 2020 17:27'	System	27 Sep 2020 00:27:38

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 6'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '15c20f6b-74bd-4763-9b9c-20b83fb7514a'	System	27 Sep 2020 23:51:37
User entered 'None (1)'	System	27 Sep 2020 23:51:37

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:27', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '15c20f6b-74bd-4763-9b9c-20b83fb7514a' User entered 'No (N)'	System	27 Sep 2020 23:51:37
	System	27 Sep 2020 23:51:37

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '15c20f6b-74bd-4763-9b9c-20b83fb7514a' User entered 'No (N)'	System	27 Sep 2020 23:51:37
	System	27 Sep 2020 23:51:37

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '15c20f6b-74bd-4763-9b9c-20b83fb7514a' User entered 'None (1)'	System	27 Sep 2020 23:51:37
	System	27 Sep 2020 23:51:37

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '15c20f6b-74bd-4763-9b9c-20b83fb7514a' User entered '27 Sep 2020 16:51'	System	27 Sep 2020 23:51:37
	System	27 Sep 2020 23:51:37

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 7'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:31', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8a6b62b8-35eb-462d-aedf-99afc9f77bb0'	System	28 Sep 2020 23:26:43
User entered 'None (1)'	System	28 Sep 2020 23:26:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8a6b62b8-35eb-462d-aedf-99afc9f77bb0' User entered 'No (N)'	System	28 Sep 2020 23:26:43
	System	28 Sep 2020 23:26:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:36', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8a6b62b8-35eb-462d-aedf-99afc9f77bb0' User entered 'No (N)'	System	28 Sep 2020 23:26:43
	System	28 Sep 2020 23:26:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:38', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8a6b62b8-35eb-462d-aedf-99afc9f77bb0'	System	28 Sep 2020 23:26:43
User entered 'None (1)'	System	28 Sep 2020 23:26:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:41', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8a6b62b8-35eb-462d-aedf-99afc9f77bb0' User entered '28 Sep 2020 16:26'	System	28 Sep 2020 23:26:43
	System	28 Sep 2020 23:26:43

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:54', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered 'None (0)'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:56', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered 'None (0)'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:21:58', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered 'None (0)'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:22:01', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered 'None (0)'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:22:03', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered 'None (0)'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:22:05', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered 'None (0)'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:22:09', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered 'No (N)'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T11:22:12', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '926385f7-5963-4899-b38b-a28d18614879' User entered '22 Sep 2020 11:22'	System	22 Sep 2020 16:22:14
	System	22 Sep 2020 16:22:14

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 11:07'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 13:37'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered 'None (0)'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:35', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered 'None (0)'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered 'None (0)'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:39', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered 'None (0)'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:41', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered 'None (0)'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered 'None (0)'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:46', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered 'No (N)'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-22T18:22:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2c984459-45ef-43ec-96ea-05ef15aea65c' User entered '22 Sep 2020 18:22'	System	22 Sep 2020 23:22:52
	System	22 Sep 2020 23:22:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '22 Sep 2020 14:32'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 2'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered 'None (0)'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered 'None (0)'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered 'None (0)'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:35', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered 'None (0)'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:38', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered 'None (0)'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:40', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered 'None (0)'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered 'No (N)'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-23T18:33:46', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'c9ca8524-a0a8-40f1-9e12-d7729649e7b2' User entered '23 Sep 2020 18:33'	System	24 Sep 2020 01:33:50
	System	24 Sep 2020 01:33:50

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 3'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered 'None (0)'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:36', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered 'None (0)'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:38', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered 'None (0)'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:41', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered 'None (0)'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:44', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered 'None (0)'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:48', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered 'None (0)'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:53', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered 'No (N)'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-24T15:04:59', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'a109537b-198e-451a-9ced-ebb843672f60' User entered '24 Sep 2020 15:04'	System	24 Sep 2020 22:05:00
	System	24 Sep 2020 22:05:00

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 4'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered 'None (0)'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:45', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered 'None (0)'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:47', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered 'None (0)'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered 'None (0)'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:51', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered 'None (0)'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:52', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered 'None (0)'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:56', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered 'No (N)'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-25T18:41:59', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2d9c7435-aa18-4497-8f84-f9b3b5887148' User entered '25 Sep 2020 18:41'	System	26 Sep 2020 01:42:05
	System	26 Sep 2020 01:42:05

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 5'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:40', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered 'None (0)'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:41', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered 'None (0)'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:42', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered 'None (0)'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered 'None (0)'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:45', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered 'None (0)'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:46', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered 'None (0)'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered 'No (N)'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-26T17:27:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b83c21ed-0fce-4e5e-8d3e-32358200e1a1' User entered '26 Sep 2020 17:27'	System	27 Sep 2020 00:28:01
	System	27 Sep 2020 00:28:01

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 6'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered 'None (0)'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:38', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered 'None (0)'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:40', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered 'None (0)'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:41', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered 'None (0)'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered 'None (0)'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:44', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered 'None (0)'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:48', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered 'No (N)'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-27T16:51:51', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '225e1886-4f19-4ad8-8054-873f5a45bdd3' User entered '27 Sep 2020 16:51'	System	27 Sep 2020 23:51:52
	System	27 Sep 2020 23:51:52

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	22 Sep 2020 16:19:10
User entered 'Day 7'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:45', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered 'None (0)'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:47', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered 'None (0)'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered 'None (0)'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:51', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered 'None (0)'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:53', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered 'None (0)'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:54', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered 'None (0)'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered 'No (N)'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-09-28T16:26:59', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '1963fdf2-2c4a-4978-bc9e-f627da647afb' User entered '28 Sep 2020 16:26'	System	28 Sep 2020 23:27:02
	System	28 Sep 2020 23:27:02

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 16:19:10

US3362210

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 16:19:10

US3362210

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:56

US3362210

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:56

US3362210

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:56

US3362210

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:18:56

US3362210

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:59

US3362210

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'I'	System	30 Sep 2020 15:18:59

US3362210

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:47:56

US3362210

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 19:47:56

US3362210

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:47:56

US3362210

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 19:47:56

US3362210

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:48:01

US3362210

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'I'	System	06 Oct 2020 19:48:01

US3362210

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:08:58

US3362210

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:08:58

US3362210

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:08:58

US3362210

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:08:58

US3362210

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:09:02

US3362210

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'I'	System	13 Oct 2020 14:09:02

US3362210

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 19:37:32

US3362210

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:37:32

US3362210

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:37:32

US3362210

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'VISIT3'	System	23 Oct 2020 19:37:32

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '13:19'	(b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '23 Oct 2020 13:19'	System	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '37.2' C	(b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '71'	(b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'bpm'	System	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '18'	(b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'breaths/min'	System	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '146'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'mmHg'	System	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '80'	(b) (4), (b) (6)	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'mmHg'	System	23 Oct 2020 19:38:20

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16

US3362210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16

US3362210

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:38:25

US3362210

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:38:25

US3362210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:37:22

US3362210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:37:22

US3362210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered '13:14'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:37:22

US3362210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered '23 Oct 2020 13:14'	System	23 Oct 2020 19:37:22

US3362210

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:16:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:33

US3362210

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'I'	System	23 Oct 2020 19:34:33

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 64'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-10-21T07:20:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'aad645c5-5e62-41c2-a312-34d02b595dbb' User entered 'No (N)'	System	21 Oct 2020 12:20:41
	System	21 Oct 2020 12:20:41

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-10-21T07:20:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'aad645c5-5e62-41c2-a312-34d02b595dbb'	System	21 Oct 2020 12:20:41
User entered 'No (N)'	System	21 Oct 2020 12:20:41

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-10-21T07:20:38', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'aad645c5-5e62-41c2-a312-34d02b595dbb' User entered '21 Oct 2020 07:20:38'	System	21 Oct 2020 12:20:41
	System	21 Oct 2020 12:20:41

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 71'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-10-30T12:30:58', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '57e34ac9-0e54-4f39-8fbb-8808d8b14a6c'	System	30 Oct 2020 17:31:14
User entered 'No (N)'	System	30 Oct 2020 17:31:14

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-10-30T12:31:06', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '57e34ac9-0e54-4f39-8fbb-8808d8b14a6c'	System	30 Oct 2020 17:31:14
User entered 'No (N)'	System	30 Oct 2020 17:31:14

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-10-30T12:31:11', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '57e34ac9-0e54-4f39-8fbb-8808d8b14a6c' User entered '30 Oct 2020 12:31:11'	System	30 Oct 2020 17:31:14
	System	30 Oct 2020 17:31:14

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 78'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-06T12:38:12', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'cfa09ae4-bef8-443e-a2d0-47dbe4e5445d'	System	06 Nov 2020 18:38:21
User entered 'No (N)'	System	06 Nov 2020 18:38:21

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-06T12:38:16', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'cfa09ae4-bef8-443e-a2d0-47dbe4e5445d'	System	06 Nov 2020 18:38:21
User entered 'No (N)'	System	06 Nov 2020 18:38:21

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-06T12:38:19', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'cfa09ae4-bef8-443e-a2d0-47dbe4e5445d' User entered '06 Nov 2020 12:38:19'	System	06 Nov 2020 18:38:21
	System	06 Nov 2020 18:38:21

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered 'Day 92'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-18T06:44:08', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fe2a8dc-66e7-4d5c-8eaa-f1eff6080ba1' User entered 'No (N)'	System	18 Nov 2020 12:44:22
	System	18 Nov 2020 12:44:22

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-18T06:44:15', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fe2a8dc-66e7-4d5c-8eaa-f1eff6080ba1'	System	18 Nov 2020 12:44:22
User entered 'No (N)'	System	18 Nov 2020 12:44:22

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-18T06:44:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2fe2a8dc-66e7-4d5c-8eaa-f1eff6080ba1' User entered '18 Nov 2020 06:44:20'	System	18 Nov 2020 12:44:22
	System	18 Nov 2020 12:44:22

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 14:05:24

US3362210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:56:51
Data entry locked.	System	21 Aug 2020 14:05:24
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 14:05:24

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-22T07:58:11', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '6b038747-5a39-4f89-9480-c679a15e0338'	System	22 Nov 2020 13:58:29
User entered 'No (N)'	System	22 Nov 2020 13:58:29

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-22T07:58:18', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '6b038747-5a39-4f89-9480-c679a15e0338'	System	22 Nov 2020 13:58:29
User entered 'No (N)'	System	22 Nov 2020 13:58:29

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-11-22T07:58:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '6b038747-5a39-4f89-9480-c679a15e0338'	System	22 Nov 2020 13:58:29
User entered '22 Nov 2020 07:58:24'	System	22 Nov 2020 13:58:29

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-01T12:09:01', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59817fe7-ddcb-454e-b6ee-3ebc2e016d40'	System	01 Dec 2020 18:09:10
User entered 'No (N)'	System	01 Dec 2020 18:09:10

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-01T12:09:05', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59817fe7-ddcb-454e-b6ee-3ebc2e016d40'	System	01 Dec 2020 18:09:10
User entered 'No (N)'	System	01 Dec 2020 18:09:10

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-01T12:09:07', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '59817fe7-ddcb-454e-b6ee-3ebc2e016d40'	System	01 Dec 2020 18:09:10
User entered '01 Dec 2020 12:09:07'	System	01 Dec 2020 18:09:10

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-06T08:01:52', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '66856839-e1c7-4320-9a99-0326f8d38ff5'	System	06 Dec 2020 14:02:01
User entered 'No (N)'	System	06 Dec 2020 14:02:01

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-06T08:01:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '66856839-e1c7-4320-9a99-0326f8d38ff5'	System	06 Dec 2020 14:02:01
User entered 'No (N)'	System	06 Dec 2020 14:02:01

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-06T08:01:58', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '66856839-e1c7-4320-9a99-0326f8d38ff5' User entered '06 Dec 2020 08:01:58'	System	06 Dec 2020 14:02:01
	System	06 Dec 2020 14:02:01

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-13T07:12:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8f691e9e-42b3-4972-a070-d05e880760fb' User entered 'No (N)'	System	13 Dec 2020 13:12:43
	System	13 Dec 2020 13:12:43

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-13T07:12:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8f691e9e-42b3-4972-a070-d05e880760fb' User entered 'No (N)'	System	13 Dec 2020 13:12:43
	System	13 Dec 2020 13:12:43

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-13T07:12:41', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '8f691e9e-42b3-4972-a070-d05e880760fb' User entered '13 Dec 2020 07:12:41'	System	13 Dec 2020 13:12:43
	System	13 Dec 2020 13:12:43

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-20T06:08:46', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '99e68bcf-36fc-4f02-a055-017dee566c19' User entered 'No (N)'	System	20 Dec 2020 12:09:17
	System	20 Dec 2020 12:09:17

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-20T06:09:05', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '99e68bcf-36fc-4f02-a055-017dee566c19' User entered 'No (N)'	System	20 Dec 2020 12:09:17

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-20T06:09:15', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '99e68bcf-36fc-4f02-a055-017dee566c19' User entered '20 Dec 2020 06:09:15'	System	20 Dec 2020 12:09:17
	System	20 Dec 2020 12:09:17

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-27T06:36:39', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b4f543d7-d12c-474b-aa1d-ac9458e39606' User entered 'No (N)'	System	27 Dec 2020 12:37:08
	System	27 Dec 2020 12:37:08

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-27T06:36:59', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b4f543d7-d12c-474b-aa1d-ac9458e39606' User entered 'No (N)'	System	27 Dec 2020 12:37:08

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2020-12-27T06:37:03', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'b4f543d7-d12c-474b-aa1d-ac9458e39606' User entered '27 Dec 2020 06:37:03'	System	27 Dec 2020 12:37:08
	System	27 Dec 2020 12:37:08

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-03T08:54:55', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'd0c576c2-8943-48a1-8799-78028c154c4f' User entered 'No (N)'	System	03 Jan 2021 14:55:17
	System	03 Jan 2021 14:55:17

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-03T08:55:08', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'd0c576c2-8943-48a1-8799-78028c154c4f'	System	03 Jan 2021 14:55:17
User entered 'No (N)'	System	03 Jan 2021 14:55:17

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-03T08:55:14', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'd0c576c2-8943-48a1-8799-78028c154c4f' User entered '03 Jan 2021 08:55:14'	System	03 Jan 2021 14:55:17
	System	03 Jan 2021 14:55:17

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:33:16', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac'	System	10 Jan 2021 14:35:33
User entered 'Yes (Y)'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:33:22', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac'	System	10 Jan 2021 14:35:33
User entered 'No (N)'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:33:48', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered 'Yes (Y)'	System	10 Jan 2021 14:35:33
	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '1'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '1'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '1'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '1'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '1'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac'	System	10 Jan 2021 14:35:33
User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '1'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:20', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '0'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac'	System	10 Jan 2021 14:35:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:42', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac'	System	10 Jan 2021 14:35:33
User entered 'Yes (Y)'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:49', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac'	System	10 Jan 2021 14:35:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-10T08:34:53', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'bab61487-fbfd-491d-b6a1-5c14cd328eac' User entered '10 Jan 2021 08:34:53'	System	10 Jan 2021 14:35:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-17T08:25:35', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f946bbb3-8c41-47e9-abde-0d708a0a5564'	System	17 Jan 2021 14:25:46
User entered 'No (N)'	System	17 Jan 2021 14:25:46

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-17T08:25:40', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f946bbb3-8c41-47e9-abde-0d708a0a5564'	System	17 Jan 2021 14:25:46
User entered 'No (N)'	System	17 Jan 2021 14:25:46

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-17T08:25:43', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'f946bbb3-8c41-47e9-abde-0d708a0a5564' User entered '17 Jan 2021 08:25:43'	System	17 Jan 2021 14:25:46

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-24T07:38:24', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '26782f55-9204-4997-86ae-482c5fb757fd' User entered 'No (N)'	System	28 Jan 2021 17:21:28
	System	28 Jan 2021 17:21:28

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-24T07:38:28', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '26782f55-9204-4997-86ae-482c5fb757fd' User entered 'No (N)'	System	28 Jan 2021 17:21:28

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-24T07:38:32', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '26782f55-9204-4997-86ae-482c5fb757fd' User entered '24 Jan 2021 07:38:32'	System	28 Jan 2021 17:21:28
	System	28 Jan 2021 17:21:28

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-31T06:43:47', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'dc726c1f-b1b1-4666-bff2-d847f60aac0a' User entered 'No (N)'	System	31 Jan 2021 12:44:01
	System	31 Jan 2021 12:44:01

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-31T06:43:52', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'dc726c1f-b1b1-4666-bff2-d847f60aac0a' User entered 'No (N)'	System	31 Jan 2021 12:44:01

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-01-31T06:43:57', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'dc726c1f-b1b1-4666-bff2-d847f60aac0a' User entered '31 Jan 2021 06:43:57'	System	31 Jan 2021 12:44:01

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-08T12:10:30', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '604afec8-1e5f-428c-9d4e-112c2c40ef38'	System	08 Feb 2021 18:12:33
User entered 'No (N)'	System	08 Feb 2021 18:12:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-08T12:10:34', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '604afec8-1e5f-428c-9d4e-112c2c40ef38'	System	08 Feb 2021 18:12:33
User entered 'No (N)'	System	08 Feb 2021 18:12:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-08T12:10:37', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '604afec8-1e5f-428c-9d4e-112c2c40ef38'	System	08 Feb 2021 18:12:33
User entered '08 Feb 2021 12:10:37'	System	08 Feb 2021 18:12:33

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-14T07:09:47', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '06600aee-11b3-4c19-9315-957f7d565230'	System	19 Feb 2021 03:56:06
User entered 'No (N)'	System	19 Feb 2021 03:56:06

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-14T07:09:50', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '06600aee-11b3-4c19-9315-957f7d565230'	System	19 Feb 2021 03:56:06
User entered 'No (N)'	System	19 Feb 2021 03:56:06

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-14T07:09:54', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '06600aee-11b3-4c19-9315-957f7d565230' User entered '14 Feb 2021 07:09:54'	System	19 Feb 2021 03:56:06

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-21T04:48:52', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63c95eb2-ab13-41c3-bc41-110653dcfc8d' User entered 'No (N)'	System	21 Feb 2021 10:49:03
	System	21 Feb 2021 10:49:03

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-21T04:48:56', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63c95eb2-ab13-41c3-bc41-110653dcfc8d' User entered 'No (N)'	System	21 Feb 2021 10:49:03
	System	21 Feb 2021 10:49:03

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-21T04:49:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '63c95eb2-ab13-41c3-bc41-110653dcfc8d' User entered '21 Feb 2021 04:49:00'	System	21 Feb 2021 10:49:03
	System	21 Feb 2021 10:49:03

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-02T12:08:35-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'cc0f0ad1-52cd-45c3-9213-a582b33c02e1' User entered 'No (N)'	System	02 Mar 2021 18:13:24
	System	02 Mar 2021 18:13:24

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-02T12:08:37-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'cc0f0ad1-52cd-45c3-9213-a582b33c02e1'	System	02 Mar 2021 18:13:24
User entered 'No (N)'	System	02 Mar 2021 18:13:24

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-02T12:08:41-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'cc0f0ad1-52cd-45c3-9213-a582b33c02e1' User entered '02 Mar 2021 12:08:41'	System	02 Mar 2021 18:13:24
	System	02 Mar 2021 18:13:24

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-07T06:13:44-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2221ec2c-cd65-4996-8691-871871f6e460' User entered 'No (N)'	System	07 Mar 2021 12:14:05
	System	07 Mar 2021 12:14:05

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-07T06:13:54-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2221ec2c-cd65-4996-8691-871871f6e460' User entered 'No (N)'	System	07 Mar 2021 12:14:05

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-07T06:13:59-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '2221ec2c-cd65-4996-8691-871871f6e460' User entered '07 Mar 2021 06:13:59'	System	07 Mar 2021 12:14:05
	System	07 Mar 2021 12:14:05

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-16T12:30:26-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0a1b6205-bf3f-4923-849f-28995d16030e'	System	16 Mar 2021 17:30:39
User entered 'No (N)'	System	16 Mar 2021 17:30:39

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-16T12:30:29-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0a1b6205-bf3f-4923-849f-28995d16030e' User entered 'No (N)'	System	16 Mar 2021 17:30:39
	System	16 Mar 2021 17:30:39

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-16T12:30:32-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '0a1b6205-bf3f-4923-849f-28995d16030e' User entered '16 Mar 2021 12:30:32'	System	16 Mar 2021 17:30:39
	System	16 Mar 2021 17:30:39

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-21T06:41:08-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '7bd866ed-05bd-495a-b3cd-38ef60b74775'	System	21 Mar 2021 11:41:18
User entered 'No (N)'	System	21 Mar 2021 11:41:18

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-21T06:41:12-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '7bd866ed-05bd-495a-b3cd-38ef60b74775'	System	21 Mar 2021 11:41:18
User entered 'No (N)'	System	21 Mar 2021 11:41:18

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-21T06:41:16-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '7bd866ed-05bd-495a-b3cd-38ef60b74775'	System	21 Mar 2021 11:41:18
User entered '21 Mar 2021 06:41:16'	System	21 Mar 2021 11:41:18

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-28T06:45:37-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9eff0abb-2c9b-4b35-b1fa-97668caf642f' User entered 'No (N)'	System	28 Mar 2021 11:45:49
	System	28 Mar 2021 11:45:49

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-28T06:45:42-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9eff0abb-2c9b-4b35-b1fa-97668caf642f' User entered 'No (N)'	System	28 Mar 2021 11:45:49
	System	28 Mar 2021 11:45:49

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-03-28T06:45:45-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '9eff0abb-2c9b-4b35-b1fa-97668caf642f' User entered '28 Mar 2021 06:45:45'	System	28 Mar 2021 11:45:49
	System	28 Mar 2021 11:45:49

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-05T20:21:30-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '05071fe0-6647-43b9-92b8-ed43bcac5ae6' User entered 'No (N)'	System	06 Apr 2021 01:21:38
	System	06 Apr 2021 01:21:38

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-05T20:21:33-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '05071fe0-6647-43b9-92b8-ed43bcac5ae6' User entered 'No (N)'	System	06 Apr 2021 01:21:38
	System	06 Apr 2021 01:21:38

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-05T20:21:36-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '05071fe0-6647-43b9-92b8-ed43bcac5ae6' User entered '05 Apr 2021 20:21:36'	System	06 Apr 2021 01:21:38
	System	06 Apr 2021 01:21:38

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-11T06:42:19-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af1f5808-4902-4dee-84e6-b7a94b292cd7'	System	11 Apr 2021 11:42:29
User entered 'No (N)'	System	11 Apr 2021 11:42:29

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-11T06:42:21-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af1f5808-4902-4dee-84e6-b7a94b292cd7'	System	11 Apr 2021 11:42:29
User entered 'No (N)'	System	11 Apr 2021 11:42:29

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-11T06:42:26-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: 'af1f5808-4902-4dee-84e6-b7a94b292cd7'	System	11 Apr 2021 11:42:29
User entered '11 Apr 2021 06:42:26'	System	11 Apr 2021 11:42:29

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-18T06:04:10-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '84e359e5-1a14-4460-9a0e-5e238b3d95e3' User entered 'No (N)'	System	18 Apr 2021 11:04:24
	System	18 Apr 2021 11:04:24

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-18T06:04:13-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '84e359e5-1a14-4460-9a0e-5e238b3d95e3' User entered 'No (N)'	System	18 Apr 2021 11:04:24
	System	18 Apr 2021 11:04:24

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-18T06:04:22-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '84e359e5-1a14-4460-9a0e-5e238b3d95e3' User entered '18 Apr 2021 06:04:22'	System	18 Apr 2021 11:04:24
	System	18 Apr 2021 11:04:24

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-25T00:42:33-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '07862f6d-98a5-49b0-83fb-9409fde67612'	System	25 Apr 2021 05:43:14
User entered 'No (N)'	System	25 Apr 2021 05:43:14

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-25T00:42:38-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '07862f6d-98a5-49b0-83fb-9409fde67612'	System	25 Apr 2021 05:43:14
User entered 'No (N)'	System	25 Apr 2021 05:43:14

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-04-25T00:42:41-05:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '07862f6d-98a5-49b0-83fb-9409fde67612'	System	25 Apr 2021 05:43:14
User entered '25 Apr 2021 00:42:41'	System	25 Apr 2021 05:43:14

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:25:16

US3362210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:16
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:25:16

US3362210

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:12:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-27T20:37:10-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '405c9734-45c6-44b7-92b6-2397efa83ec5'	System	28 Feb 2021 02:37:19
User entered 'No (N)'	System	28 Feb 2021 02:37:19

US3362210

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:12:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FD98AB36-B94E-4AD9-9A9E-EEBD3F6D9176)', Time: '2021-02-27T20:37:15-06:00', User OID: 'PatientReportedOutcome (US3362210)', ODM File OID: '405c9734-45c6-44b7-92b6-2397efa83ec5' User entered '28 Feb 2021 02:37:15'	System	28 Feb 2021 02:37:19
	System	28 Feb 2021 02:37:19

US3362210

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:24:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:39:56

US3362210

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:24:55
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:39:56

US3362210

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:24:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:39:56

US3362210

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:24:55
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:39:56

US3362210

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:24:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:40:01

US3362210

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:18:16
User entered 'I'	System	16 Nov 2020 15:40:01

US3362210

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:00:57

US3362210

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '18 Dec 2020'	(b) (4), (b) (6)	22 Jan 2021 20:00:57

US3362210

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:00:57

US3362210

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:00:57

US3362210

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:01:02

US3362210

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User entered 'I'	System	22 Jan 2021 20:01:02

US3362210

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:05:23

US3362210

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per CDM RQ: Thank you for the response. Please ensure to submit PD since contact occurred outside the original schedule of events.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:30:32
Query 'Per CDM RQ: Thank you for the response. Please ensure to submit PD since contact occurred outside the original schedule of events.' answered with 'PD logged.' (Site from DM).	Alexandra Caillouet (b) (4)	26 Jan 2021 23:38:55
User opened query 'Per CDM RQ: Thank you for the response. Please ensure to submit PD since contact occurred outside the original schedule of events.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 18:11:08
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	26 Jan 2021 18:03:31
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Attempted to contact subject on 22 Jan 2021, but they did not answer.' (Site from System).	Alexandra Caillouet (b) (4)	25 Jan 2021 21:06:44
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	25 Jan 2021 21:05:23
User entered '25 Jan 2021'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:05:23

US3362210

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Contact Made (CONTACT MADE)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:05:23

US3362210

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	25 Jan 2021 21:05:23

US3362210

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Jan 2021 21:06:54

US3362210

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User entered 'I'	System	25 Jan 2021 21:06:54

US3362210

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 20:28:24

US3362210

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:55:48
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Attempted Subject 3 times, Sent Certified Letter, Patient Retuned called on 08MAR2021. Completed DAY 179 Call OOW' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 20:31:31
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Mar 2021 20:28:24
User entered '8 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 20:28:24

US3362210

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:28:24

US3362210

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 20:28:24

US3362210

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 20:28:30

US3362210

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:50:26
User entered 'I'	System	08 Mar 2021 20:28:30

US3362210

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:03

US3362210

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:03

US3362210

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:03

US3362210

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered 'VISIT4'	System	19 Mar 2021 18:57:03

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered empty.	System	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered empty.	System	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered empty.	System	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered empty.	System	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered empty.	System	30 Mar 2021 18:57:55

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17

US3362210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17

US3362210

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:43

US3362210

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:43

US3362210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:57

US3362210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:57

US3362210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12:38'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:57:57

US3362210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered '19 Mar 2021 12:38'	System	19 Mar 2021 18:57:57

US3362210

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:58:03

US3362210

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:55:17
User entered 'I'	System	19 Mar 2021 18:58:03

US3362210

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:20:31

US3362210

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:20:31

US3362210

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:20:31

US3362210

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:20:31

US3362210

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 13:20:35

US3362210

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 13:20:35

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:41

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12:45'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:41

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:59
User entered '12 Jan 2021 12:45'	System	12 Jan 2021 19:55:41

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:41

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:41

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 1 (Day 1)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '8 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'I'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 19:56:40
User entered empty.	Alexandra Caillouet	12 Jan 2021 19:55:56
	(b) (4)	

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	12 Jan 2021 19:56:40
User entered empty.	System	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 19:56:40
User entered empty.	Alexandra Caillouet	12 Jan 2021 19:55:56
	(b) (4)	

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:56

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 2 (Day 2)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '9 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'I'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 19:56:40
User entered empty.	Alexandra Caillouet	12 Jan 2021 19:56:06
	(b) (4)	

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	12 Jan 2021 19:56:40
User entered empty.	System	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 19:56:40
User entered empty.	Alexandra Caillouet	12 Jan 2021 19:56:06
	(b) (4)	

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:06

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 3 (Day 3)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '10 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'I'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 19:56:40
User entered empty.	Alexandra Caillouet	12 Jan 2021 19:56:15
	(b) (4)	

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	12 Jan 2021 19:56:40
User entered empty.	System	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 19:56:40
User entered empty.	Alexandra Caillouet	12 Jan 2021 19:56:15
	(b) (4)	

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:15

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 4 (Day 4)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '11 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'I'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered missing code ND - Not Done.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:56:40

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 5 (Day 5)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '36.8' C	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:20

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 6 (Day 6)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '13 Jan 2021'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '94'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98.7' F	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	13 Jan 2021 21:10:53

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '95'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:46:17

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 21:19:56
User entered '8 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:19:43

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 9 (Day 9)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '16 Jan 2021'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User entered '%'	System	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97.1' F	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:04
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Crystal Rowell (b) (4)	18 Jan 2021 19:21:25

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per CDM: Please consider updating this question once test result is available. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 11:16:22
Query 'Per CDM: Please consider updating this question once test result is available. Thank you!' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	16 Jan 2021 14:38:13
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	16 Jan 2021 14:38:03
User opened query 'Per CDM: Please consider updating this question once test result is available. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:44:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 10:44:16
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:42
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 19:58:37
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 19:58:37

US3362210

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:23:09
User entered '0'	System	16 Jan 2021 14:38:03

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:18
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:41:08

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:18
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '10:00'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:41:08

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:18
User entered '29 Aug 2020 10:00'	System	01 Sep 2020 17:41:08

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:18
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:41:08

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:51

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:18
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:41:08

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per CDM; it appears that both the contact date and symptom start date are the same. Please confirm this is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:55:05
Query 'Per CDM; it appears that both the contact date and symptom start date are the same. Please confirm this is the actual symptom start date and update accordingly.' answered with 'per eCRF guidelines, symptom D1 is the same as illness D1' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:26:45
User opened query 'Per CDM; it appears that both the contact date and symptom start date are the same. Please confirm this is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 00:47:13
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '37' C	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:42:50

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '30 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '96'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '99.9' F	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:49:48

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '99' F	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:56:12

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 21:50:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:36:26

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:02:27

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '98'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:29:05

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Day 8 (Day 8)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '5 Sep 2020'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '97'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User entered '%'	System	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '99.1' F	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:12:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'None (None)'	Amy Thomassie (b) (4)	06 Sep 2020 12:59:23

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
Query 'Per CDM: a diagnostic test was conducted however there is no Unscheduled Visit recorded. Please reconcile and update accordingly. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:44:57
User opened query 'Per CDM: a diagnostic test was conducted however there is no Unscheduled Visit recorded. Please reconcile and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 00:47:33
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User closed query 'Per CDM: a diagnostic test was conducted however there is no Illness Visit recorded. Please reconcile and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Oct 2020 14:52:20
Query 'Per CDM: a diagnostic test was conducted however there is no Illness Visit recorded. Please reconcile and update accordingly. ' answered with 'illness visit added' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:41:54
User opened query 'Per CDM: a diagnostic test was conducted however there is no Illness Visit recorded. Please reconcile and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:45:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 11:23:22
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	06 Sep 2020 13:00:04
Query 'Data is required. Please complete.' answered with 'still pending ' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:01:10
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 17:59:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:45

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:12:51

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:48
User entered '0'	System	06 Sep 2020 13:00:04

US3362210

Folder: Covid-19 Assessment 29 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:12:51

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:22:53
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'No (N)'	Amy Thomassie (b) (4)	18 Sep 2020 16:14:22

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 29AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:34:11
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'swab collected on 29Aug2020. Please provide clarification if query is in reference to Swab collection or Saliva collection as Swab collection is recorded in EDC' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 21:55:37
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 04:42:16
User accepted default value 'Day 3 (Day 3)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 02,04SEP2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 06:24:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 02,04SEP2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession Number: 1F60A2D' (Site from DM).	Alexandra Caillouet (b) (4)	04 Dec 2020 22:27:44
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 02,04SEP2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:17:16
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:58:01
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'Illness visit conducted on 29Aug2020, day 3 saliva collected on 31Aug2020' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:36:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:34:37
User entered '31 Aug 2020'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User accepted default value 'Day 5 (Day 5)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 09:45:49
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'DCR will be sent.' (Site from DM).	Alexandra Caillouet (b) (4)	02 Apr 2021 15:29:49
User entered '02 Sep 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	02 Apr 2021 15:28:51
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:18:58
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:52:16
User entered '29 Aug 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 22:52:20

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession Number: 1F60A2D ' (Site from DM).	Alexandra Caillouet (b) (4)	07 Jan 2021 17:22:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 05:00:50
User entered '02 Sep 2020'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:52:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Updated. Subject used Day 5 tube to collect Day 3 saliva on 29 AUG 2020.' (Site from DM).	Alexandra Caillouet (b) (4)	08 Jan 2021 23:00:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:38:16
User accepted default value 'Day 7 (Day 7)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample under Illness visit day 7 is dated 04SEP2020 in EDC, however the same is dated as 29SEP2020 in PPD Central lab. Please reconcile the correct Date and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 05:58:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample under Illness visit day 7 is dated 04SEP2020 in EDC, however the same is dated as 29SEP2020 in PPD Central lab. Please reconcile the correct Date and update if applicable. Else clarify, thank you.' answered with 'EDC correct, DCF submitted' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 15:40:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample under Illness visit day 7 is dated 04SEP2020 in EDC, however the same is dated as 29SEP2020 in PPD Central lab. Please reconcile the correct Date and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 03:10:37
User entered '04 Sep 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	02 Apr 2021 15:28:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:52:20
User entered '29 Sep 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 23:01:05

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession Number: 1F60A2D ' (Site from DM).	Alexandra Caillouet (b) (4)	07 Jan 2021 17:22:51
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 05:01:00
User closed query 'Per GCL Lab Recon: GCL has a Saliva Day 7 sample with date of 29AUG2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:19:40
Query 'Per GCL Lab Recon: GCL has a Saliva Day 7 sample with date of 29AUG2020. Please reconcile or clarify' answered with 'confirmed 04sep2020' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:33:37
User opened query 'Per GCL Lab Recon: GCL has a Saliva Day 7 sample with date of 29AUG2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 14:53:02
User entered '04 Sep 2020'	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User accepted default value 'Day 9 (Day 9)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'NA (COVID-19 Negative) (NA)'	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User accepted default value 'Day 14 (Day 14)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'NA (COVID-19 Negative) (NA)'	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User accepted default value 'Day 21 (Day 21)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'NA (COVID-19 Negative) (NA)'	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User accepted default value 'Day 28 (Day 28)'	Amy Thomassie (b) (4) (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'NA (COVID-19 Negative) (NA)'	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:58
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Amy Thomassie (b) (4)	16 Oct 2020 18:39:31

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '14 Jan 2021'	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '16 Jan 2021'	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 21:17:48
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	10 Feb 2021 21:17:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:39
User entered empty.	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 21:17:48
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	10 Feb 2021 21:17:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:39
User entered empty.	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 21:17:48
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	10 Feb 2021 21:17:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:39
User entered empty.	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 21:17:48
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	10 Feb 2021 21:17:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:39
User entered empty.	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:12:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:12:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 21:17:48
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	10 Feb 2021 21:17:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 21:17:39
User entered empty.	Alexandra Caillouet	10 Feb 2021 21:17:39
	(b) (4)	

US3362210

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	10 Feb 2021 21:17:39

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:12
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	16 Oct 2020 18:29:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:12
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '29 Aug 2020'	Amy Thomassie (b) (4)	16 Oct 2020 18:29:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:12
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Clinic (Clinic)'	Amy Thomassie (b) (4)	16 Oct 2020 18:29:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:12
User entered 'SICKD1'	System	16 Oct 2020 18:29:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '29 Aug 2020'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '11:00'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User entered '29 Aug 2020 11:00'	System	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '181.0' cm	(b) (4)	
	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12
	(b) (4)	
DataPoint set to visible.	System	16 Oct 2020 18:29:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '108.7' kg	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12
DataPoint set to visible.	System	16 Oct 2020 18:29:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '37.0' C	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Oral (Oral)'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '62'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User entered 'bpm'	System	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '18'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User entered 'breaths/min'	System	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '138'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User entered 'mmHg'	System	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '90'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21
User entered 'mmHg'	System	16 Oct 2020 18:30:12

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:21

US3362210

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:31

US3362210

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '29 Aug 2020'	Amy Thomassie (b) (4)	16 Oct 2020 18:30:31

US3362210

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:12:51

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	16 Oct 2020 18:31:01

US3362210

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '29 Aug 2020'	Amy Thomassie (b) (4)	16 Oct 2020 18:31:01

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:50:25

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:50:25

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:50:25

US3362210

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	12 Jan 2021 19:50:25

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12:50'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Jan 2021 12:50'	System	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '181' cm	Alexandra Caillouet	12 Jan 2021 19:54:50
	(b) (4)	
DataPoint set to visible.	System	12 Jan 2021 19:50:25

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '108.7' kg	Alexandra Caillouet	12 Jan 2021 19:54:50
	(b) (4)	
DataPoint set to visible.	System	12 Jan 2021 19:50:25

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '36.8' C	Alexandra Caillouet	12 Jan 2021 19:54:50
	(b) (4)	

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Oral (Oral)'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '74'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '16'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '130'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '77'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Jan 2021 19:54:50

US3362210

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:01

US3362210

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '12 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:01

US3362210

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:12:51

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 07:26:37
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Saliva log updated.' (Site from DM).	Alexandra Caillouet (b) (4)	10 Feb 2021 21:18:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:25:00
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:10

US3362210

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 07:26:38
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Saliva Log updated.' (Site from DM).	Alexandra Caillouet (b) (4)	10 Feb 2021 21:18:45
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:25:26
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:44:47

US3362210

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:12:51

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'Accession #1F60A2D Collected 12Jan2021 per PPD specimen received report' (Site from DM).	Amy Thomassie (b) (4)	29 Jan 2021 21:04:29
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:35:13
User entered '12 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 19:55:10

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 20:59:22
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 20:59:22
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Alexandra Caillouet	25 Jan 2021 20:59:22
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 20:59:22

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 21:00:01
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:26:09

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 21:00:01
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:26:09

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 21:00:01
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	25 Jan 2021 21:00:01
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	25 Jan 2021 21:00:01
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	25 Jan 2021 21:00:01
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	25 Jan 2021 21:00:01
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User entered empty.	System	25 Jan 2021 21:00:01

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User entered empty.	System	25 Jan 2021 21:00:01

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 20:59:34
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 20:59:34
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '07:19'	Alexandra Caillouet	25 Jan 2021 20:59:34
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User entered '25 Jan 2021 07:19'	System	25 Jan 2021 20:59:34

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	25 Jan 2021 20:59:47
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:51

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '25 Jan 2021'	Alexandra Caillouet	25 Jan 2021 20:59:47
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
	(b) (4)	
User entered '07:51'	Alexandra Caillouet	25 Jan 2021 20:59:47
	(b) (4)	

US3362210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:51

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:00:16
User entered '25 Jan 2021 07:51'	System	25 Jan 2021 20:59:47

US3362210

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:12:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:33:01
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:18:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:32:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:41:16

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User closed query 'Per MM, please confirm if the subject was diagnosed with COVID-19. If not, please add the individual symptoms as separate entries.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 16:40:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 19:28:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 19:28:33
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 19:27:27
Query 'Per MM, please confirm if the subject was diagnosed with COVID-19. If not, please add the individual symptoms as separate entries.' answered with 'Swab from 29 AUG 2020 Illness visit was negative.' (Site from DM).	Alexandra Caillouet	15 Dec 2020 19:26:56
	(b) (4)	
Coding entries removed.	Alexandra Caillouet	15 Dec 2020 19:26:51
	(b) (4)	
User entered 'Upper Respiratory Illness' reason for change: Data Entry Error	Alexandra Caillouet	15 Dec 2020 19:26:51
	(b) (4)	
User opened query 'Per MM, please confirm if the subject was diagnosed with COVID-19. If not, please add the individual symptoms as separate entries.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 16:28:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:39:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:39:49
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 21:38:48
User entered 'Covid-19 symptoms'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '22 Aug 2020' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 22:45:40
	(b) (4)	
User entered '21 Aug 2020' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 22:44:46
	(b) (4)	
User entered '22 Aug 2020' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 22:44:11
	(b) (4)	
User entered '28 Aug 2020'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 18:55:41
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Alexandra Caillouet	10 Dec 2020 22:45:48
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 22:44:11
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User entered empty.	System	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '30 Aug 2020'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 18:55:43
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Alexandra Caillouet	10 Dec 2020 22:45:53
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 22:44:11
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User entered empty.	System	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 21:38:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 21:38:43
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:38:43
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 21:38:25
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'Per DM CLR - RQ: Site's response noted. However, the AE term is UPPER RESPIRATORY INFECTION and not COVID-19. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:53:40
Query 'Per DM CLR - RQ: Site's response noted. However, the AE term is UPPER RESPIRATORY INFECTION and not COVID-19. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'Upper respiratory infection is correct AE, patient was not COVID 19 positive' (Site from DM).	Crystal Rowell (b) (4)	13 Jan 2021 22:27:04
User opened query 'Per DM CLR - RQ: Site's response noted. However, the AE term is UPPER RESPIRATORY INFECTION and not COVID-19. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:47:33
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 15:40:44

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Ibuprofen taken for fever associated with COVID-19 Symptoms. ' (Site from DM).	Alexandra Caillouet (b) (4)	10 Dec 2020 22:48:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 10:23:16
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User entered '0'	System	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23
User entered '0'	System	16 Nov 2020 21:38:25

US3362210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:23

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 13:21:59
User entered		
'USA-US112-2021-mRNA-1273-P301000005'	System	13 Jan 2021 13:21:54
User entered 'New'	(b) (4), (b) (6)	13 Jan 2021 13:21:54

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 18:45:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 18:45:54
	(b) (4)	
Data point term sent to Coder	System	22 Jan 2021 18:55:55
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 18:55:39
	(b) (4), (b) (6)	
User entered 'PNEUMONIA right lower lobe' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 18:55:39
	(b) (4), (b) (6)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 20:02:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 20:02:02
	(b) (4)	
Data point term sent to Coder	System	12 Jan 2021 20:01:26
User entered 'Pneumonia'	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered '8 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:56:18
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:54:18
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 18:57:37
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).		
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Jan 2021 18:57:23
User entered '14 Jan 2021' reason for change: Data Entry Error	System	22 Jan 2021 18:57:23
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	System	22 Jan 2021 18:56:18
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 18:56:18
	(b) (4), (b) (6)	20 Jan 2021 18:50:17
	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:57:23
User entered 'Grade 4 (Grade 4)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	12 Jan 2021 20:02:17
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Jan 2021 20:00:52
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered '0'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:47:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Crystal Rowell (b) (4) (b) (4)	13 Jan 2021 22:27:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Jan 2021 20:02:17
User entered '1' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	12 Jan 2021 20:02:17
User entered '0'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '8 Jan 2021' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Jan 2021 22:27:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '9 Jan 2021' reason for change: Data Entry Error	Crystal Rowell (b) (4)	13 Jan 2021 22:27:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'Per CDM: Please complete all applicable forms for this subject. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:43:36
Query 'Per CDM: Please complete all applicable forms for this subject. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	14 Jan 2021 20:43:12
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:42:59
User opened query 'Per CDM: Please complete all applicable forms for this subject. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 19:47:05
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'Per CDM: Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:28:34
Query 'Per CDM: Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'Dose 2 of IP was given 22SEP2020. AE occurred after last dose of IP and before open label dose on 25JAN2021' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	29 Jan 2021 21:08:49
User opened query 'Per CDM: Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 06:10:01
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered '1'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:54:23
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 18:58:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 18:57:23
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:50:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:00:52
	(b) (4)	

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
User closed query 'Per DM CLR: Narrative = GIVEN CEFTRIAZONE AND 30 CC/KG FLUID BOLUS. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:02:37
User closed query 'Per DM CLR: Narrative = PLACED ON 2L NC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:02:33
User closed query 'Per DM CLR: Narrative = SEPSIS WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:02:06
Query 'Per DM CLR: Narrative = GIVEN CEFTRIAZONE AND 30 CC/KG FLUID BOLUS. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Will add to con med log.' (Site from DM).	Alexandra Caillouet (b) (4)	24 Mar 2021 19:56:05
Query 'Per DM CLR: Narrative = SEPSIS WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'This is not a procedure. This is a panel of lab orders placed by the hospital. there is no place to add these labs in EDC. Copy of medical records with these labs and results have already been sent. ' (Site from DM).	Alexandra Caillouet (b) (4)	24 Mar 2021 19:55:35
Query 'Per DM CLR: Narrative = PLACED ON 2L NC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Will add to con med log.' (Site from DM).	Alexandra Caillouet (b) (4)	24 Mar 2021 19:50:56
User opened query 'Per DM CLR: Narrative = GIVEN CEFTRIAZONE AND 30 CC/KG FLUID BOLUS. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:14:50

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = SEPSIS WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:14:44
User opened query 'Per DM CLR: Narrative = PLACED ON 2L NC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:14:38
User closed query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 16:40:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 15:18:54
Query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' answered with 'Med records sent to Safety_Moderna@iqvia.com. ' (Site from DM).	Alexandra Caillouet (b) (4)	03 Feb 2021 20:03:43
User entered 'Presented to hospital for shortness of breath, fever, nausea, and vomiting. Found to be hypoxic at 87% and placed on 2L NC, febrile to 101.7. Sepsis workup started and found right sided pneumonia. No white count. Rapid COVID negative. Given ceftriaxone and azithromycin as well as 30 cc/kg fluid bolus.' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	03 Feb 2021 20:03:29

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Records sent to Safety_Moderna@iqvia.com' (Site from Safety).	Alexandra Caillouet (b) (4)	03 Feb 2021 19:57:33
User closed query 'PV Query: PV Query: Was the subject tested for COVID-19 while in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:06:53
Query 'PV Query: PV Query: Was the subject tested for COVID-19 while in the hospital? If yes, please provide results.' answered with 'COVID-19 result was negative in the hospital. ' (Site from Safety).	Alexandra Caillouet (b) (4)	02 Feb 2021 23:48:50
User opened query 'PV Query: PV Query: Was the subject tested for COVID-19 while in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 18:38:27
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:50:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Jan 2021 14:36:36
User opened query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 14:36:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'Medical records requested. Will update once hospital records become available. ' (Site from System).	Alexandra Caillouet (b) (4)	12 Jan 2021 20:01:55
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Jan 2021 20:00:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

2297 of 2694

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Jan 2021 20:00:52

US3362210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 20:42:59

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Exacerbation of asthma - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 19:16:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 19:16:04
	(b) (4)	
Data point term sent to Coder	System	22 Jan 2021 19:15:18
User entered 'asthma exacerbation'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '08 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User entered empty.	System	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User entered empty.	System	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 23:38:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 23:38:15
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Alexandra Caillouet	26 Jan 2021 23:38:15
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 19:14:17
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User closed query 'Per CDM: Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 17:11:21
Query 'Per CDM: Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	03 Feb 2021 19:09:22
User entered 'None (NONE)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	03 Feb 2021 19:09:16
User opened query 'Per CDM: Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 06:09:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:10:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User entered '0'	System	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27
User entered '1'	System	22 Jan 2021 19:14:17

US3362210

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:32:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:12:51

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:33:01
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:41:48

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Aug 2020 06:52:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 06:52:13
Data point term sent to Coder	System	21 Aug 2020 20:44:14
User entered 'fluticasone propionate salmeterol'	(b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Asthma'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '250/50/1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mcg/puff'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 20:44:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 20:46:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:46:16
Data point term sent to Coder	System	21 Aug 2020 20:45:19
User entered 'montelukast'	(b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Asthma'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '10'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 20:45:16

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 15:18:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:18:45
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Sep 2020 15:18:04 22 Sep 2020 15:18:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:48:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:48:19
Data point term sent to Coder User entered 'ALBUTEROL HFA'	System (b) (4), (b) (6)	21 Aug 2020 20:47:22 21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Asthma'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '2'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:30:42
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Data updated per query resolution. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:18:09
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 15:18:03
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:32:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:47:02

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Nov 2020 15:37:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 15:37:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:49:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:49:20
Data point term sent to Coder	System	21 Aug 2020 20:48:24
User entered 'ALBUTEROL'	(b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Asthma'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '2.5/3'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg/ml'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:48:04

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 20:50:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:50:22
Data point term sent to Coder	System	21 Aug 2020 20:49:27
User entered 'atorvastatin'	(b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'hyperlipidemia'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '40'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 20:49:05

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 20:51:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:51:23
Data point term sent to Coder	System	21 Aug 2020 20:50:31
User entered 'Pantoprazole'	(b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:31:28
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:24:31
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:33:18
User entered 'Gerd (acid reflux)'	(b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '40'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 20:50:14

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Jan 2021 19:20:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	22 Jan 2021 19:20:03
Data point term sent to Coder	System	22 Jan 2021 19:19:25
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 19:19:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 14:26:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	29 Dec 2020 14:26:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 22:49:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	10 Dec 2020 22:49:55
Data point term sent to Coder	System	10 Dec 2020 22:49:05
Coding entries removed.	Alexandra Caillouet (b) (4)	10 Dec 2020 22:48:12

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[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: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 13:35:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 13:35:50
Data point term sent to Coder	System	06 Sep 2020 13:35:19
User entered 'ibuprofen'	Amy Thomassie (b) (4) (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User closed query 'Per CDM: Kindly review if this field as there is no corresponding AE or Med History that matches this indication. Please update if needed, else provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:38:20
Query 'Per CDM: Kindly review if this field as there is no corresponding AE or Med History that matches this indication. Please update if needed, else provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:19:28
User entered 'UPPER RESPIRATORY ILLNESS' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:19:21
User opened query 'Per CDM: Kindly review if this field as there is no corresponding AE or Med History that matches this indication. Please update if needed, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:53:30
User entered 'COVID-19 Symptoms' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	10 Dec 2020 22:48:12
User entered 'fever'	Amy Thomassie (b) (4) (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '400'	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	(b) (4) Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4)	
	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once daily (QD)'	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	(b) (4) Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (22Aug2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:37:29
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (22Aug2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'start date corrected ' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	27 Feb 2021 14:19:17
User entered '22 Aug 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	27 Feb 2021 14:18:26
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (22Aug2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:52:26
User entered '21 Aug 2020'	Amy Thomassie (b) (4) (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '26 Aug 2020'	Amy Thomassie (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:37:43
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated to no' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	27 Feb 2021 14:19:31
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	27 Feb 2021 14:18:26
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:53:00

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES; however there is no record in eDiary with this indication within the timeframe. Please review and update if this should be changed to "No". Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:13:18
Query 'Per DM CLR: Was this medication taken for solicited event? = YES; however there is no record in eDiary with this indication within the timeframe. Please review and update if this should be changed to "No". Otherwise, please provide clarification.'	(b) (4), (b) (6)	06 Oct 2020 19:38:28
answered with 'Ibuprofen was taken for fever reported on diary dose 1. Medication was not reported in ediary but medication was confirmed on day 8 telephone call.' (Site from DM).		
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES; however there is no record in eDiary with this indication within the timeframe. Please review and update if this should be changed to "No". Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 15:04:57
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User entered '1'	System	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User entered '1'	System	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:54
User entered '804 (804)'	System	06 Sep 2020 13:34:24

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:52:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:52:59
Data point term sent to Coder	System	12 Jan 2021 20:12:34
User entered 'Guaifenesin/Dextromethorphan Hydrobromide'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Pneumonia'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '600/30'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'twice daily (BID)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '10 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:06:47
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 19:06:47
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:12:23
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User entered '2'	System	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User entered '1'	System	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:16:58
User entered '804 (804)'	System	12 Jan 2021 20:12:23

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	12 Jan 2021 20:27:58
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	12 Jan 2021 20:27:58
Data point term sent to Coders	System	12 Jan 2021 20:27:41
User entered 'Azithromycin'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Pneumonia'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '250'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once daily (QD)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '10 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:07:18
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:07:18
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User entered '1'	System	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User entered '1'	System	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:03
User entered '804 (804)'	System	12 Jan 2021 20:27:27

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:43:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:43:09
Data point term sent to Coder	System	12 Jan 2021 20:28:42
User entered 'Benzonatate'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Pneumonia'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '100'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'as needed (PRN)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Oral (ORAL)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '10 Jan 2021'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:07:37
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:07:37
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User entered empty.	System	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User entered empty.	System	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:10
User entered empty.	System	12 Jan 2021 20:28:25

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Jan 2021 22:56:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 22:56:06
Data point term sent to Coder	System	22 Jan 2021 19:09:02
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 19:08:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 21:55:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 21:55:59
Data point term sent to Coder	System	12 Jan 2021 20:29:42
User entered 'Albuterol/ipratropium'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:29:38

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'PNEUMONIA/asthma exacerbation'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:08:25
User entered 'Pneumonia'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 103/18). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:38:00
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 103/18). ' answered with 'updated ' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	27 Feb 2021 14:24:12
User entered '2.5/0.5' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	27 Feb 2021 14:24:02
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 103/18). ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:53:26
User entered '90'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:29:38

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	27 Feb 2021 14:24:02
	(b) (4)	
User entered 'ug (ug)'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'four times daily (QID)'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered empty.	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered '10 Jan 2021'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered '0'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:08:25
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Jan 2021 20:29:38

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:08:25
User entered empty.	Alexandra Caillouet (b) (4)	12 Jan 2021 20:29:38

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	12 Jan 2021 20:29:38
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Jan 2021 20:29:38

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Jan 2021 20:29:38

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Jan 2021 20:29:38

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 20:15:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	24 Mar 2021 20:15:40
Data point term sent to Coder	System	24 Mar 2021 20:15:13
User entered 'Lactated Ringers'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Pneumonia Right lower Lobe'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User closed query 'Per DM CLR: Please review the dose recorded as this is unexpectedly high for a bolus administration. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:39:57
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	09 Apr 2021 00:56:22
Query 'Per DM CLR: Please review the dose recorded as this is unexpectedly high for a bolus administration. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Confirmed that was the dose recorded in medical records provided to the study site from the hospital. ' (Site from DM).	Alexandra Caillouet (b) (4)	07 Apr 2021 15:44:04
User opened query 'Per DM CLR: Please review the dose recorded as this is unexpectedly high for a bolus administration. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:28:03
User entered '3063'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mL (mL)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 15:44:37
User entered 'other (OTHER)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 15:43:12
User entered 'once (ONCE)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alexandra Caillouet	07 Apr 2021 15:44:37
User entered 'Continuous' reason for change: Data Entry Error	(b) (4)	
	Alexandra Caillouet	07 Apr 2021 15:43:12
User entered empty.	(b) (4)	
	Alexandra Caillouet	24 Mar 2021 20:14:31
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '8 Jan 2021'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '8 Jan 2021'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User entered empty.	System	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User entered empty.	System	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:19
User entered empty.	System	24 Mar 2021 20:14:31

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Mar 2021 07:10:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:10:17
Data point term sent to Coder	System	24 Mar 2021 20:20:21
User entered 'Ceftraixone'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Pneumonia right lower lobe'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'I'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'g (g)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once (ONCE)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '8 Jan 2021'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '8 Jan 2021'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User entered empty.	System	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User entered empty.	System	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:24
User entered empty.	System	24 Mar 2021 20:19:50

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 11:35:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 11:35:32
Data point term sent to Coder	System	24 Mar 2021 20:21:24
User entered 'Azithromycin'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Pneumonia Right lower Lobe'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '500'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'mg (mg)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'once (ONCE)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered empty.	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '8 Jan 2021'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '0'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered '8 Jan 2021'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User entered empty.	System	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User entered empty.	System	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:17:30
User entered empty.	System	24 Mar 2021 20:20:44

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 04:56:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 04:56:47
Data point term sent to Coder	System	24 Mar 2021 20:26:32
User entered 'Oxygen'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:25:39

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Pneumonia Right Lower Lobe'	(b) (4) Alexandra Caillouet (b) (4)	24 Mar 2021 20:25:39

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered '2'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'Other (OTHER)'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Determine if "liters/min" is more appropriate. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:40:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Determine if "liters/min" is more appropriate. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	07 Apr 2021 15:49:55
User entered 'LITERS/min' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 15:49:38
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Determine if "liters/min" is more appropriate. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:29:16
User entered 'Liter'	Alexandra Caillouet (b) (4)	24 Mar 2021 20:25:39

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'once (ONCE)'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered empty.	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Alexandra Caillouet (b) (4)	24 Mar 2021 20:25:39

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered empty.	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered '8 Jan 2021'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered '0'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered '8 Jan 2021'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	24 Mar 2021 20:25:39
	(b) (4)	

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 20:25:39

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 20:25:39

US3362210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:12:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 20:25:39

US3362210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:12:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:56:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:50:26

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'USA-US112-2021-MRNA-1273-P301000005'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Jordan'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Whatley'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '5326 O'donovan dr'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'baton rouge'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '70808'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:00:05
User entered 'US'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Feb 2021 15:21:00
User entered '3'	System	25 Jan 2021 19:56:01
User entered '2'	System	14 Jan 2021 13:00:17
User entered '1'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'USA-US112-2021-MRNA-1273-P301000005'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Jordan'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Whatley'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '5326 O'donovan dr'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'baton rouge'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '70808'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:00:05
User entered 'US'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Feb 2021 15:21:00
User entered '3'	System	25 Jan 2021 19:56:01
User entered '2'	System	14 Jan 2021 13:00:17
User entered '1'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:12:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '13/Jan/2021 13:22'	(b) (4) System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:12:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:00:05
User entered 'I'	(b) (4), (b) (6)	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'USA-US112-2021-MRNA-1273-P301000005'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Jordan'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Whatley'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '5326 O'donovan dr'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'baton rouge'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '70808'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:00:05
User entered 'US'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Feb 2021 15:21:00
User entered '3'	System	25 Jan 2021 19:56:01
User entered '2'	System	14 Jan 2021 13:00:17
User entered '1'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:12:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '14/Jan/2021 13:00'	(b) (4) System	14 Jan 2021 13:00:17

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:12:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:46
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 13:00:17

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'USA-US112-2021-MRNA-1273-P301000005'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Jordan'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Whatley'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '5326 O'donovan dr'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'baton rouge'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '70808'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:00:05
User entered 'US'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Feb 2021 15:21:00
User entered '3'	System	25 Jan 2021 19:56:01
User entered '2'	System	14 Jan 2021 13:00:17
User entered '1'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:12:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '25/Jan/2021 19:55'	(b) (4) System	25 Jan 2021 19:56:01

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:12:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 15:19:55
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 19:56:01

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'USA-US112-2021-MRNA-1273-P301000005'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Yes (Y)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'No (N)'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Jordan'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'Whatley'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '5326 O'donovan dr'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered 'baton rouge'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:22:11
User entered '70808'	System	13 Jan 2021 13:21:54

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:00:05
User entered 'US'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Feb 2021 15:21:00
User entered '3'	System	25 Jan 2021 19:56:01
User entered '2'	System	14 Jan 2021 13:00:17
User entered '1'	System	13 Jan 2021 13:22:29

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:12:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered '04/Feb/2021 10:20'	(b) (4) System	04 Feb 2021 15:21:00

US3362210

Folder: SAE USA-US112-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:12:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:33:38
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:21:00