

US3622142 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:11:43

All time stamps listed in this document are displayed in GMT

US3622142

Form: Participant Creation

Data signed: (b) (4) 13 Sep 2020 16:31:18

Generated On: 10 Jun 2021 09:11:43

[Participant ID](#)

US3622142

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

US3622142

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Sep 2020 16:31:28

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Condition	POST MENOPAUSE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Condition	ASTHMA (MILD)
Start date (dd MMM yyyy)	UN (b) (6) 1951
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)	(b) (6) 1951
Start Year (derived)	1951
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:26 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 10:26
Height (<i>xxx.x</i>)	62.5 in
Weight (<i>xxx.x</i>)	175 lb
BMI (<i>xxx.x</i>)	31.56370 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*) 3 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Sep 2020 16:31:28

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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

COSMETOLOGY, NOT
WORKING BUT SOCIALLY
ACTIVE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Sep 2020 16:31:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189738

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

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)	3 SEP 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 10:26
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

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)	3 SEP 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 12:32
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 3 SEP 2020

What was the treatment time? (00:00-23:59) 12:02 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 12:02

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	10:55 (24 HR)
Collection date and time (derived)	3 SEP 2020 10:55

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	3 SEP 2020 11:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Sep 2020 16:31:28

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

03 SEP 2020 12:52

PC Open Date & Time

03 SEP 2020 12:22

PC Close Date & Time

03 SEP 2020 14:52

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °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	03 SEP 2020 19:18
PC Open Date & Time	03 SEP 2020 15:47
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

04 SEP 2020 19:47

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

05 SEP 2020 22:33

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

06 SEP 2020 18:15

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

07 SEP 2020 18:44

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

09 SEP 2020 20:58

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

03 SEP 2020 12:52

PC Open Date & Time

03 SEP 2020 12:22

PC Close Date & Time

03 SEP 2020 14:52

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

03 SEP 2020 19:18

PC Open Date & Time

03 SEP 2020 15:47

PC Close Date & Time

04 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:47

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 22:33

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 18:45

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 20:58

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 12:53
PC Open Date & Time	03 SEP 2020 12:22
PC Close Date & Time	03 SEP 2020 14:52

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 19:19
PC Open Date & Time	03 SEP 2020 15:47
PC Close Date & Time	04 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

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 ☒

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:48
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

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 ☒

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:34
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

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 ☒

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EAB) (1725)

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:16
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

EAB) (1725)

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US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:45
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

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
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

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 ☒

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:59
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3622142

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 12:58:49

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 12:58:49

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 12:58:49

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 12:58:49

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	VISIT2

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

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)	1 OCT 2020
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 08:48
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 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

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

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)	1 OCT 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:40
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3622142

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 10:08 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 10:08

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

US3622142

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 OCT 2020

Collection time (00:00-23:59)

09:10 (24 HR)

Collection date and time (derived)

1 OCT 2020 09:10

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:14	1 OCT 2020 09:14
Nasopharyngeal Swab 2	No		

US3622142

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 12:11:06

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

98.4 °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

01 OCT 2020 10:44

PC Open Date & Time

01 OCT 2020 10:28

PC Close Date & Time

01 OCT 2020 12:58

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.5 °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	01 OCT 2020 18:58
PC Open Date & Time	01 OCT 2020 13:53
PC Close Date & Time	02 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

02 OCT 2020 12:23

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:11

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

04 OCT 2020 17:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

05 OCT 2020 13:46

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

06 OCT 2020 12:11

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

08 OCT 2020 00:45

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

01 OCT 2020 10:44

PC Open Date & Time

01 OCT 2020 10:28

PC Close Date & Time

01 OCT 2020 12:58

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

01 OCT 2020 18:59

PC Open Date & Time

01 OCT 2020 13:53

PC Close Date & Time

02 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

02 OCT 2020 12:23

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

03 OCT 2020 12:11

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

04 OCT 2020 17:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

05 OCT 2020 13:46

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

06 OCT 2020 12:12

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

08 OCT 2020 00:45

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 10:45
PC Open Date & Time	01 OCT 2020 10:28
PC Close Date & Time	01 OCT 2020 12:58

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 19:00
PC Open Date & Time	01 OCT 2020 13:53
PC Close Date & Time	02 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

92 of 3867

EAB) (1725)

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:24
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

94 of 3867

EAB) (1725)

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

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 ☒

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 17:05
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

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 ☒

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 13:47
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

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 ☒

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

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 ☒

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 00:46
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3622142

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 19:59:43

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 19:59:43

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 19:59:43

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 19:59:43

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Oct 2020 14:54:23

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 14:54:23

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 16:26:22

Generated On: 10 Jun 2021 09:11:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Nov 2020 16:26:22

Generated On: 10 Jun 2021 09:11:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 10:56
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622142

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 16:26:22

Generated On: 10 Jun 2021 09:11:43

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.

US3622142

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Nov 2020 16:26:22

Generated On: 10 Jun 2021 09:11:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	11:10 (24 HR)
Collection date and time (derived)	29 OCT 2020 11:10

US3622142

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:26:22

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

13 NOV 2020 00:30:11

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

19 NOV 2020 16:03:02

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 00:02:28

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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	08 DEC 2020 12:27:06
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

16 DEC 2020 11:41:09

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

19 DEC 2020 00:02:52

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

29 DEC 2020 13:49:45

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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	02 JAN 2021 00:02:30
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

13 JAN 2021 14:30:47

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

17 JAN 2021 11:48:54

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 16:28:28

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	False
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	True
Runny nose	True
Nausea	True
Vomiting	False
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 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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

02 FEB 2021 03:29:47

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

06 FEB 2021 00:02:49

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 FEB 2021 12:33:50
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

24 FEB 2021 08:03:23

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 15:03:40

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 MAR 2021 08:52:58
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 22:27:32
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 22:53:51

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

31 MAR 2021 08:51:36

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

03 APR 2021 00:08:33

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

10 APR 2021 00:02:26

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

19 APR 2021 21:02:29

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 11:40:21

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

01 MAY 2021 20:32:53

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 <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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 <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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Patient Cloud Open Date & Time	05 FEB 2022 00:01
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Patient Cloud Close Date & Time	09 FEB 2022 23:59
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US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 <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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 <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"/>

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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="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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Patient Cloud Open Date & Time	23 JUL 2022 00:01
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Patient Cloud Close Date & Time	27 JUL 2022 23:59
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US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3622142

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:11:43

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		02 MAR 2021 15:04:03

US3622142

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:04:41

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:04:41

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:04:41

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:04:41

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 14:03:57

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 14:03:57

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 19:55:21

Generated On: 10 Jun 2021 09:11:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 APR 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

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 19:55:21

Generated On: 10 Jun 2021 09:11:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 APR 2021
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	7 APR 2021 10:30
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 19:55:21

Generated On: 10 Jun 2021 09:11:43

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.

US3622142

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 19:55:21

Generated On: 10 Jun 2021 09:11:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 APR 2021
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	7 APR 2021 10:40

US3622142

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 19:55:21

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 14:03:56

Generated On: 10 Jun 2021 09:11:43

Date of Contact	2 FEB 2021
Time of Contact	10:00
Date and Time of Contact (derived)	2 FEB 2021 10:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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	26 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input checked="" 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"/>

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EAB) (1725)

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US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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	27 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input checked="" 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)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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	28 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input checked="" 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"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.5 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 type="radio"/>
	Moderate	<input checked="" 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"/>

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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 type="checkbox"/>
Day 10	<input checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021
------	------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.5 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 type="radio"/>
	Moderate	<input checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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	05 FEB 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98 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 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"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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	6 FEB 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
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 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"/>
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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" 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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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	7 FEB 2021
------	------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 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 checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021
------	------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 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 checked="" 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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021
------	------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 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 checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.2 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 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 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 checked="" 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"/>

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	98 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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 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 checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2021
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	97.5 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

	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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Date of Visit	2 FEB 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	29 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 checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	MOUNT SINAI HOSPITAL
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 29 JAN 2021

End Date 29 JAN 2021

Oxygen Saturation 90 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date _____

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment 29 JAN 2021

Radiographical Evidence Yes ☒
No ☐

Date of Assessment 29 JAN 2021

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	Yes	2 FEB 2021
Day 7	Yes	4 FEB 2021
Day 9	Yes	6 FEB 2021
Day 14	Yes	11 FEB 2021
Day 21	Yes	18 FEB 2021
Day 28	Yes	25 FEB 2021

US3622142

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 14:03:56

Generated On: 10 Jun 2021 09:11:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 14:03:56

Generated On: 10 Jun 2021 09:11:43

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) _____

Height (xxx.x) _____

Weight (xxx.x) _____

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) _____

US3622142

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 14:03:56

Generated On: 10 Jun 2021 09:11:43

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.

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Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 14:03:56

Generated On: 10 Jun 2021 09:11:43

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 10:23
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3622142

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Mar 2021 21:55:18

Generated On: 10 Jun 2021 09:11:43

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 FEB 2021

US3622142

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

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

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

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3622142

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:12:15

Generated On: 10 Jun 2021 09:11:43

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3622142

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Height	62.5 in
Weight	175 lb
BMI (xxx.x)	31.56370

US3622142

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Height	62.5 in
Weight	175 lb
BMI (xxx.x)	31.56370
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)	15 JAN 2021
Time of assessment (00:00-23:59)	07:48 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 07:48
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3622142

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Height	62.5 in
Weight	175 lb
BMI (xxx.x)	31.56370
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)	15 JAN 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 08:55
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3622142

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

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

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.

US3622142

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

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 08:23 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 08:23

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

US3622142

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

07:55 (24 HR)

Collection date and time (derived)

15 JAN 2021 07:55

US3622142

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	08:00
Collection Date and Time (derived)	15 JAN 2021 08:00

US3622142

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

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622142

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622142

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3622142

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3622142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

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.

US3622142

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

Was study treatment given? Yes ☐
No ☐

If No, reason not given

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

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

What was the study treatment? (Unblinded) _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3622142

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622142

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Jan 2021 15:08:08

Generated On: 10 Jun 2021 09:11:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

MUSCLE ACHES AT INJECTION
SITE

Was this a medically-attended AE?

Yes ☐
No ☒

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

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

Yes ☐
No ☒

Start date (dd MMM yyyy)

15 JAN 2021

Start time (00:00-23:59)

10:00 (24 HR)

AE start date and time (derived)

15 JAN 2021 10:00

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

15 JAN 2021

End time (00:00-23:59)

21:00 (24 HR)

AE End Date and Time (derived)

15 JAN 2021 21:00

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 ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID	USA-US085-2021-MRNA-1273-P30 1000009
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	26 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)	15 FEB 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 type="radio"/> Grade 4 <input checked="" 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)	29 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	31 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SHORTNESS OF BREATH ON EXERTION
Narrative	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

PARTICIPANT CONTACTED
SITE STATING THAT THEY
WENT TO EMERGENCY ROOM
ON 01/29/2021 BECAUSE THEY
WERE EXPERIENCING COVID-19
SYMPTOMS. PARTICIPANT
THEN WAS TESTED COVID-19
POSITIVE. THEY WERE
ADMITTED TO HOSPITAL FROM
01/29/2021 TO 1/31/2021.

UPDATE: HOSPITAL ADMISSION
FOR COVID 19 JANUARY 29,
2021 THROUGH JANUARY 31,
2021

THE PARTICIPANT WENT TO
THE ER ON JANUARY 29, 2021
WITH CHIEF COMPLAINT OF
COUGH, SHORTNESS OF
BREATH, AND FATIGUE. PER ER
DOCUMENTATION SHE WAS
93% ON ROOM AIR AND
DECREASED TO 90% AFTER 45
SECONDS OF STRESS TESTING.
SHE WAS TESTED FOR COVID
19 AND WAS FOUND TO BE
POSITIVE. PARTICIPANT WAS
ADMITTED AND ADMITTING
DIAGNOSES INCLUDED
HYPOXIA, ACUTE
RESPIRATORY DISEASE DUE TO
COVID-19 VIRUS, AND
COVID-19. ADDITIONAL
DIAGNOSES INCLUDED

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

HYPONATREMIA AND
HYPERGLYCEMIA. RELEVANT
LAB RESULTS ON 01/29/2021
INCLUDED SARS-COV-2RNA
POSITIVE, SODIUM 124,
GLUCOSE 404, D-DIMER 0.55, PT
100, INR 13, CRP 100. CHEST
X-RAY ON 01/29/2021 WITH
SMALL PATCHY OPACITIES AT
THE PERIPHERY OF BILATERAL
MID TO LOWER LUNGS. THE
PARTICIPANT RECEIVED
CONVALESCENT PLASMA ON
JANUARY 29, 2021. SHE
REPORTS THAT SHE RECEIVED
2 DOSES OF REMDESIVIR
HOWEVER, THE HOSPITAL
RECORDS SHOW THAT THE
INFUSION WAS STOPPED DUE
TO ITCHING AND RASH.
ADDITIONAL MEDICATIONS
GIVEN FOR COVID 19
INCLUDED DOXYCYCLINE
100MG BID, DEXAMETHASONE
6MG DAILY, COLCHICINE
0.6MG, VITAMIN C 1,000 MG
DAILY, VITAMIN D 1,250MCG,
AND ZINC SULFATE 220MG
DAILY. LOVENOX 40MG
SUBCUTANEOUS WAS GIVEN
FOR THE PREVENTION OF
BLOOD CLOTS AND HUMALOG
2UNITS AND LANTUS 6 UNITS
WERE GIVEN FOR
HYPERGLYCEMIA. THE

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

PARTICIPANT HAS A
DOCUMENTED HISTORY OF
ASTHMA, DM, AND
HYPERTENSION. SHE WAS
DISCHARGED HOME ON
JANUARY 31, 2021 IN STABLE
CONDITION.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID USA-US085-2021-MRNA-1273-P30
1000009

Adverse event ACUTE HYPOXEMIC
RESPIRATORY FAILURE
SECONDARY TO COVID-19

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) 6 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 9 FEB 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 True

Hospital Admission Date (dd MMM yyyy) 6 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 9 FEB 2021

Admitted to ICU? Yes ☐
No ☒

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
<hr/>		
Persistent or significant disability or incapacity		False
<hr/>		
Congenital anomaly or birth defect		False
<hr/>		
Other medically important event		False
<hr/>		
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Other action taken (check all that apply)		
<hr/>		
None		False
<hr/>		
Concomitant Medication		True
<hr/>		
Concomitant Procedure		False
<hr/>		
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input type="radio"/>
	Recovered/Resolved with Sequelae	<input checked="" type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SHORTNESS OF BREATH ON EXERTION	
<hr/>		
Narrative		

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

MEDICAL RECORDS FROM HOSPITAL ADMISSION HAVE BEEN REVIEWED. THE PARTICIPANT WENT TO THE ER FOR WORSENING SOB ON FEBRUARY 06, 2021. RECORDS STATE THAT SHE PRESENTED WITH OXYGEN SATURATION AT 89% ON ROOM AIR WHICH IMPROVED TO 98% WITH 2L NASAL CANULA. FINDINGS INCLUDED WORSENING COVID RELATED PNEUMONIA AND HYPOXIA AND SHE WAS ADMITTED. SIGNIFICANT LABS FROM FEBRUARY 06, 2021 INCLUDED SARS-COV-2RNA POSITIVE, SODIUM 130 (L), POTASSIUM 3.2 (L), CRP 53.8 (H), LACTIC ACID 2.2 (H), D-DIMER 1.37 (H). CHEST X-RAY ON FEBRUARY 06, 2021 WITH BILATERAL PERIPHERAL AIRSPACE OPACITIES CONCERNING FOR MULTIFOCAL PNEUMONIA, SLIGHTLY MORE PROMINENT COMPARED TO PRIOR AND CONSISTENT WITH PATIENT'S POSITIVE COVID-19 STATUS. CTA OF THE CHEST ON FEBRUARY 09, 2021 WAS NEGATIVE FOR PE BUT REVEALED EXTENSIVE BILATERAL MULTIFOCAL

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

CONSOLIDATIVE AND GROUND
GLASS OPACITIES. SHE WAS
FOUND TO HAVE BILATERAL
LOWER EXTREMITY EDEMA
FOR WHICH SHE WAS GIVEN IV
LASIX. EKG ON 02/06/2021 AND
ECHOCARDIOGRAM ON
02/09/2021 WERE BOTH
NORMAL. MEDICATIONS GIVEN
DURING ADMISSION INCLUDE
ALBUTEROL INHALER,
ASPIRIN, COLCHICINE,
DECADRON, DOXYCYCLINE,
LOVENOX, LASIX, ROBITUSSIN,
HUMALOG, POTASSIUM
CHLORIDE AND VANCOMYCIN.
SHE REMAINED WITH OXYGEN
SATURATION AT 95% OR
GREATER WHILE ADMITTED
AND WAS DISCHARGED HOME
IN STABLE CONDITION ON
02/09/2021.

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

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

WORSENING HYPERGLYCEMIA

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)

29 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)

9 FEB 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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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)	_____

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

HYPONATREMIA

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)

29 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)

12 MAR 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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

GENERALIZED ITCHING

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)

29 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)

31 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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

RASH (RELATED TO
REMDESIVIR)

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)

29 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)

31 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 ☐

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

PNEUMONIA

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)

29 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)

12 MAR 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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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)	_____

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID	
Adverse event	LACTIC ACIDOSIS
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)	6 FEB 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)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID	
Adverse event	HYPOKALEMIA
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)	6 FEB 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)	8 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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)	

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

BILATERAL LOWER
EXTREMITY EDEMA

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)

8 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 MAR 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 ☐

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID

Adverse event

SHORTNESS OF BREATH ON
EXERTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 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)

02 MAR 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 ☐

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

AEID	
Adverse event	HYPOTHYROIDISM
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)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Sep 2020 16:31:18

Generated On: 10 Jun 2021 09:11:43

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

Yes ☒

No ☐

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

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 850

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication VITAMIN E

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

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

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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 2012	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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 2012	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 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

YEARLY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication ADVAIR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 500/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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 FEB 2017	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		26 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) 28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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)	06 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 6

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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)	06 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 0.6

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	06 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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)	29 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1,000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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)		15 FEB 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"/>

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1250

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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)	15 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication ZINC SULFATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 220

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF CLOTS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		30 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) 30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 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)		30 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication PROTONIX

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 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) 31 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication WORSENING HYPERGLYCEMIA

Dose per administration 2

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

If dose unit is Other, specify UNIT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 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) 31 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication WORSENING HYPERGLYCEMIA

Dose per administration 6

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

If dose unit is Other, specify UNIT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 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) 31 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ITCHY; RASH
(RELATED TO REMDESIVIR)

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		31 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)		31 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication ACUTE HYPOXEMIC
RESPIRATORY FAILURE
SECONDARY TO COVID-19

Dose per administration 180

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

EVERY 4 HOURS AS NEEDED.

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)	6 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF BLOOD CLOTS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 9 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 0.6

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		7 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 7 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 6

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 7 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication DOXYCYCLINE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	6 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF BLOOD CLOTS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		7 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication BILATERAL LOWER
EXTREMITY EDEMA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	9 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication ROBITUSSIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		6 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication WORSENING HYPERGLYCEMIA

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)	7 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication ISOVUE 300

Prophylaxis Yes ☐
No ☒

Indication CONTRAST FOR CTA

Dose per administration 65

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 40

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

If dose unit is Other, specify MEQ

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		6 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		IVPB
Start date (dd MMM yyyy)		6 FEB 2021
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		6 FEB 2021
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	7 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 9 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 50,000

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

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EAB) (1725)

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)		7 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 7 FEB 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"/>

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication ZINC SULFATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 220

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 ☐

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EAB) (1725)

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 FEB 2021
Start date completely unknown		False
Ongoing?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 9 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="radio"/>	803 <input type="radio"/>
	804 <input checked="" type="radio"/>	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE HYPOXEMIC
RESPIRATORY FAILURE
SECONDARY TO COVID-19

Dose per administration 2

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

If dose unit is Other, specify LITER

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 ☐

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EAB) (1725)

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US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" 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)	6 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL LOWER
EXTREMITY EDEMA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

	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)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 MAR 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"/>

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 16 Apr 2021 02:23:55

Generated On: 10 Jun 2021 09:11:43

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

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 14:03:56

Generated On: 10 Jun 2021 09:11:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 JAN 2021	CONVALESCENT PLASMA	Adverse Event	
29 JAN 2021	EKG	Diagnostic	
29 JAN 2021	CHEST X-RAY	Diagnostic	
06 FEB 2021	EKG	Diagnostic	
06 FEB 2021	CHEST X-RAY	Diagnostic	
07 FEB 2021	CHEST X-RAY	Diagnostic	
09 FEB 2021	CTA CHEST WITH CONTRAST	Diagnostic	
09 FEB 2021	ECHOCARDIOGRAM	Diagnostic	
29 JAN 2021	COMPLETE METABOLIC PANEL	Diagnostic	
29 JAN 2021	SARS-COV-2RNA TEST	Diagnostic	
29 JAN 2021	D-DIMER LAB	Diagnostic	
29 JAN 2021	PT LAB	Diagnostic	
29 JAN 2021	INR LAB	Diagnostic	
29 JAN 2021	CRP LAB	Diagnostic	
6 FEB 2021	COMPLETE METABOLIC PANEL	Diagnostic	
6 FEB 2021	CRP LAB	Diagnostic	
6 FEB 2021	LACTIC ACID LAB	Diagnostic	
6 FEB 2021	D-DIMER LAB	Diagnostic	

US3622142

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:11:43

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 ☐

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	03/FEB/2021 12:12
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

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/FEB/2021 09:39
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

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/FEB/2021 14:07
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

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/FEB/2021 16:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/FEB/2021 10:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/FEB/2021 09:16
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

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/FEB/2021 16:18
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

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Mar 2021 20:09:55

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000009
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:55
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

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 14:03:57

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000012
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 14:03:57

Generated On: 10 Jun 2021 09:11:43

SAEID	USA-US085-2021-MRNA-1273-P301000012
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	09/FEB/2021 12:32
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

US3622142 (Prod: University of Miami)

US3622142

Form: Participant Creation

Generated On: 10 Jun 2021 09:11:43

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:44:45
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'US3622142'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:48

US3622142

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:29:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 04:56:19
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 22:07:19
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 10:35:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 16:09:51

US3622142

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:29:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:49

US3622142

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[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 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:29:18
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Sep 2020 16:09:51

US3622142

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'SCRN'	System	03 Sep 2020 16:09:51

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:50

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '69'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'YEARS'	System	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered '69'	System	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:19:53

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:51
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'Sep 2020'	System	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered '2020'	System	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:51
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:51
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:51
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:51
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:51
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:03

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:30:51
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:49

US3622142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'I'	System	03 Sep 2020 16:10:10

US3622142

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:31:13
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:11:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:31:22
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:08:02

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 22:10:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:10:45
Data point term sent to Coder	System	10 Sep 2020 22:09:16
User entered 'hypertension'	(b) (4), (b) (6)	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'Jan 1985'	System	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered '1985'	System	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	10 Sep 2020 22:08:31

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 22:10:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:10:45
Data point term sent to Coder	System	10 Sep 2020 22:09:19
User entered 'diabetes'	(b) (4), (b) (6)	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'Jan 2012'	System	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered '2012'	System	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	10 Sep 2020 22:09:01

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 21:38:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:44
Data point term sent to Coder	System	23 Nov 2020 16:10:56
User entered 'post menopause'	Junlin Long (b) (4) (b) (4)	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	Junlin Long (b) (4)	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'l'	Junlin Long (b) (4)	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User closed query 'Per DM CLR: Please review the stop date of this [POST MENOPAUSE] MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:20:00
Query 'Per DM CLR: Please review the stop date of this [POST MENOPAUSE] MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:35:22
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	15 Jan 2021 15:35:14
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	15 Jan 2021 15:34:55
User entered 'Yes (Y)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:34:55
User opened query 'Per DM CLR: Please review the stop date of this [POST MENOPAUSE] MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 02:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	Junlin Long (b) (4)	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '0' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	15 Jan 2021 15:35:14
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	23 Nov 2020 16:10:10

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Jan 2021 19:15:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 19:15:20
Data point term sent to Coder	System	22 Jan 2021 18:58:56
User entered 'asthma (mild)'	Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	24 Feb 2021 16:24:01
User entered 'UN ^{(b) (6)} 1951' reason for change: Per Query Resolution	Junlin Long (b) (4)	24 Feb 2021 16:24:01
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	22 Jan 2021 18:58:37
User entered 'un UNK 1951'	System	22 Jan 2021 18:58:37
	Junlin Long (b) (4)	22 Jan 2021 18:58:37
	(b) (4)	

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '0'	Junlin Long (b) (4)	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	Junlin Long (b) (4)	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:10:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '0'	Junlin Long (b) (4)	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered (b) (6) 1951'	System	24 Feb 2021 16:24:01
User entered 'Jan 1951'	System	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered '1951'	System	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered empty.	System	22 Jan 2021 18:58:37

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '10:26'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered '3 Sep 2020 10:26'	System	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '62.5' in	(b) (4), (b) (6)	10 Sep 2020 22:10:08
DataPoint set to visible.	System	03 Sep 2020 16:10:10

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '175' lb	(b) (4), (b) (6)	10 Sep 2020 22:10:08
DataPoint set to visible.	System	03 Sep 2020 16:10:10

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered '31.56370'	System	10 Sep 2020 22:10:08
DataPoint set to visible.	System	03 Sep 2020 16:10:10

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'kg/m2'	System	10 Sep 2020 22:10:08
DataPoint set to visible.	System	03 Sep 2020 16:10:10

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'bpm'	System	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'breaths/min'	System	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'mmHg'	System	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User entered 'mmHg'	System	10 Sep 2020 22:10:08

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09

US3622142

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09

US3622142

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:02
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:17

US3622142

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:02
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:10:17

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:58:34
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'recorded in MH' (Site from DM).	Junlin Long (b) (4)	23 Nov 2020 16:10:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 23:41:35
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:43

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:20
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:12:27

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'cosmetology, not working but socially active'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:33:56
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:11

US3622142

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:27

US3622142

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:27

US3622142

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:21
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:10:27

US3622142

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'VISIT1'	System	03 Sep 2020 16:10:27

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:59

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '189738'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:59

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:59

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

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)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:44

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

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)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:44

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:44

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:44

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:14:44

US3622142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:31
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'No (N)'	Junlin Long	29 Sep 2020 14:10:35
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:11:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:11:14

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '10:26'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '3 Sep 2020 10:26'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 22:17:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 22:17:22
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 22:17:22
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 22:17:10
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '74'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'bpm'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '17'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'breaths/min'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '132'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '86'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '12:32'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '3 Sep 2020 12:32'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '71'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'bpm'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '17'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'breaths/min'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '126'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:34:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '91'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	10 Sep 2020 22:17:10

US3622142

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:34

US3622142

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:31
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:34

US3622142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:17
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:17
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:17
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:17
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:17
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '12:02'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '3 Sep 2020 12:02'	System	03 Sep 2020 16:47:58

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Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:17
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

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[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:17
User entered 'ONCE'	System	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 16:47:58

US3622142

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:47

US3622142

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:17:47

US3622142

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 22:17:56
User entered '10:55' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 22:17:56
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 22:17:47
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 22:17:47

US3622142

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '3 Sep 2020 10:55'	System	10 Sep 2020 22:17:56
User entered empty.	System	10 Sep 2020 22:17:47

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:58
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:04
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:04
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered '11:15'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '3 Sep 2020 11:15'	System	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:04
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:04
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered empty.	System	10 Sep 2020 22:18:14

US3622142

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:18:19

US3622142

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	10 Sep 2020 22:18:19

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:51:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2081120b-b2f0-4b14-8bbb-aadb8966c3f7'	System	03 Sep 2020 16:52:25
User entered 'Yes (Y)'	System	03 Sep 2020 16:52:25

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:04', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2081120b-b2f0-4b14-8bbb-aadb8966c3f7'	System	03 Sep 2020 16:52:25
User entered '98.6'	System	03 Sep 2020 16:52:25

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:12', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2081120b-b2f0-4b14-8bbb-aadb8966c3f7'	System	03 Sep 2020 16:52:25
User entered 'No (N)'	System	03 Sep 2020 16:52:25

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:21', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2081120b-b2f0-4b14-8bbb-aadb8966c3f7'	System	03 Sep 2020 16:52:25
User entered '03 Sep 2020 12:52'	System	03 Sep 2020 16:52:25

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 12:22'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:17:37', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6a913b6c-07ed-4324-a65a-9970a2a9bf77'	System	03 Sep 2020 23:18:07
User entered 'Yes (Y)'	System	03 Sep 2020 23:18:07

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:17:50', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6a913b6c-07ed-4324-a65a-9970a2a9bf77'	System	03 Sep 2020 23:18:07
User entered '97.4'	System	03 Sep 2020 23:18:07

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:17:55', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6a913b6c-07ed-4324-a65a-9970a2a9bf77'	System	03 Sep 2020 23:18:07
User entered 'No (N)'	System	03 Sep 2020 23:18:07

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:03', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6a913b6c-07ed-4324-a65a-9970a2a9bf77'	System	03 Sep 2020 23:18:07
User entered '03 Sep 2020 19:18'	System	03 Sep 2020 23:18:07

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 15:47'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 2'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:46:52', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c34b8cc-817c-4d40-b17c-d3b7829c03b5'	System	04 Sep 2020 23:47:19
User entered 'Yes (Y)'	System	04 Sep 2020 23:47:19

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c34b8cc-817c-4d40-b17c-d3b7829c03b5'	System	04 Sep 2020 23:47:19
User entered '97.5'	System	04 Sep 2020 23:47:19

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:07', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c34b8cc-817c-4d40-b17c-d3b7829c03b5'	System	04 Sep 2020 23:47:19
User entered 'No (N)'	System	04 Sep 2020 23:47:19

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:15', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c34b8cc-817c-4d40-b17c-d3b7829c03b5'	System	04 Sep 2020 23:47:19
User entered '04 Sep 2020 19:47'	System	04 Sep 2020 23:47:19

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 3'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:32:47', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '1e618216-61f5-48ed-bdd5-4a23fb402966'	System	06 Sep 2020 02:33:13
User entered 'Yes (Y)'	System	06 Sep 2020 02:33:13

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:32:59', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '1e618216-61f5-48ed-bdd5-4a23fb402966'	System	06 Sep 2020 02:33:13
User entered '97.3'	System	06 Sep 2020 02:33:13

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:04', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '1e618216-61f5-48ed-bdd5-4a23fb402966'	System	06 Sep 2020 02:33:13
User entered 'No (N)'	System	06 Sep 2020 02:33:13

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:08', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '1e618216-61f5-48ed-bdd5-4a23fb402966'	System	06 Sep 2020 02:33:13
User entered '05 Sep 2020 22:33'	System	06 Sep 2020 02:33:13

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 4'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:15:23', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd47ef9a7-48c9-4eb3-9c8a-ef156031df07'	System	06 Sep 2020 22:15:43
User entered 'Yes (Y)'	System	06 Sep 2020 22:15:43

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:15:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd47ef9a7-48c9-4eb3-9c8a-ef156031df07'	System	06 Sep 2020 22:15:43
User entered '97.3'	System	06 Sep 2020 22:15:43

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:15:35', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd47ef9a7-48c9-4eb3-9c8a-ef156031df07'	System	06 Sep 2020 22:15:43
User entered 'No (N)'	System	06 Sep 2020 22:15:43

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:15:39', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd47ef9a7-48c9-4eb3-9c8a-ef156031df07'	System	06 Sep 2020 22:15:43
User entered '06 Sep 2020 18:15'	System	06 Sep 2020 22:15:43

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 5'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:44:29', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c571a88-0919-48ad-aedf-e4154bfd788c'	System	07 Sep 2020 22:44:56
User entered 'Yes (Y)'	System	07 Sep 2020 22:44:56

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:44:39', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c571a88-0919-48ad-aedf-e4154bfd788c'	System	07 Sep 2020 22:44:56
User entered '97.2'	System	07 Sep 2020 22:44:56

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:44:44', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c571a88-0919-48ad-aedf-e4154bfd788c'	System	07 Sep 2020 22:44:56
User entered 'No (N)'	System	07 Sep 2020 22:44:56

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:44:47', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c571a88-0919-48ad-aedf-e4154bfd788c'	System	07 Sep 2020 22:44:56
User entered '07 Sep 2020 18:44'	System	07 Sep 2020 22:44:56

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 6'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 7'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:57:47', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'db098121-9f9b-42eb-a509-ea4514c27f66'	System	10 Sep 2020 00:58:11
User entered 'Yes (Y)'	System	10 Sep 2020 00:58:11

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:57:58', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'db098121-9f9b-42eb-a509-ea4514c27f66'	System	10 Sep 2020 00:58:11
User entered '97.1'	System	10 Sep 2020 00:58:11

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:03', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'db098121-9f9b-42eb-a509-ea4514c27f66'	System	10 Sep 2020 00:58:11
User entered 'No (N)'	System	10 Sep 2020 00:58:11

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:06', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'db098121-9f9b-42eb-a509-ea4514c27f66'	System	10 Sep 2020 00:58:11
User entered '09 Sep 2020 20:58'	System	10 Sep 2020 00:58:11

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '9222dcad-c703-4d59-b39b-c225bc59fcac'	System	03 Sep 2020 16:52:57
User entered 'None (1)'	System	03 Sep 2020 16:52:57

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:37', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '9222dcad-c703-4d59-b39b-c225bc59fcac'	System	03 Sep 2020 16:52:57
User entered 'No (N)'	System	03 Sep 2020 16:52:57

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:43', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '9222dcad-c703-4d59-b39b-c225bc59fcac'	System	03 Sep 2020 16:52:57
User entered 'No (N)'	System	03 Sep 2020 16:52:57

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:47', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '9222dcad-c703-4d59-b39b-c225bc59fcac'	System	03 Sep 2020 16:52:57
User entered 'None (1)'	System	03 Sep 2020 16:52:57

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:53', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '9222dcad-c703-4d59-b39b-c225bc59fcac'	System	03 Sep 2020 16:52:57
User entered '03 Sep 2020 12:52'	System	03 Sep 2020 16:52:57

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 12:22'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:10', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '11590969-f836-4eb7-b5fe-7cfe531817a6'	System	03 Sep 2020 23:18:30
User entered 'None (1)'	System	03 Sep 2020 23:18:30

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:14', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '11590969-f836-4eb7-b5fe-7cfe531817a6'	System	03 Sep 2020 23:18:30
User entered 'No (N)'	System	03 Sep 2020 23:18:30

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:18', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '11590969-f836-4eb7-b5fe-7cfe531817a6'	System	03 Sep 2020 23:18:30
User entered 'No (N)'	System	03 Sep 2020 23:18:30

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:22', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '11590969-f836-4eb7-b5fe-7cfe531817a6'	System	03 Sep 2020 23:18:30
User entered 'None (1)'	System	03 Sep 2020 23:18:30

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:26', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '11590969-f836-4eb7-b5fe-7cfe531817a6'	System	03 Sep 2020 23:18:30
User entered '03 Sep 2020 19:18'	System	03 Sep 2020 23:18:30

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 15:47'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 2'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:22', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a87147a9-42e6-4cc2-b6fa-9ce6492b6e55'	System	04 Sep 2020 23:47:47
User entered 'None (1)'	System	04 Sep 2020 23:47:47

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:27', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a87147a9-42e6-4cc2-b6fa-9ce6492b6e55'	System	04 Sep 2020 23:47:47
User entered 'No (N)'	System	04 Sep 2020 23:47:47

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a87147a9-42e6-4cc2-b6fa-9ce6492b6e55'	System	04 Sep 2020 23:47:47
User entered 'No (N)'	System	04 Sep 2020 23:47:47

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:36', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a87147a9-42e6-4cc2-b6fa-9ce6492b6e55'	System	04 Sep 2020 23:47:47
User entered 'None (1)'	System	04 Sep 2020 23:47:47

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:43', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a87147a9-42e6-4cc2-b6fa-9ce6492b6e55'	System	04 Sep 2020 23:47:47
User entered '04 Sep 2020 19:47'	System	04 Sep 2020 23:47:47

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 3'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:16', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c3c906d-bfa3-4feb-9178-6bf655bef065'	System	06 Sep 2020 02:33:40
User entered 'None (1)'	System	06 Sep 2020 02:33:40

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:20', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c3c906d-bfa3-4feb-9178-6bf655bef065'	System	06 Sep 2020 02:33:40
User entered 'No (N)'	System	06 Sep 2020 02:33:40

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:24', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c3c906d-bfa3-4feb-9178-6bf655bef065'	System	06 Sep 2020 02:33:40
User entered 'No (N)'	System	06 Sep 2020 02:33:40

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:29', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c3c906d-bfa3-4feb-9178-6bf655bef065'	System	06 Sep 2020 02:33:40
User entered 'None (1)'	System	06 Sep 2020 02:33:40

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:34', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6c3c906d-bfa3-4feb-9178-6bf655bef065'	System	06 Sep 2020 02:33:40
User entered '05 Sep 2020 22:33'	System	06 Sep 2020 02:33:40

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 4'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:15:49', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b987d18e-d4dd-4ba2-af41-4f2348061022'	System	06 Sep 2020 22:16:08
User entered 'None (1)'	System	06 Sep 2020 22:16:08

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:15:53', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b987d18e-d4dd-4ba2-af41-4f2348061022'	System	06 Sep 2020 22:16:08
User entered 'No (N)'	System	06 Sep 2020 22:16:08

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:15:57', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b987d18e-d4dd-4ba2-af41-4f2348061022'	System	06 Sep 2020 22:16:08
User entered 'No (N)'	System	06 Sep 2020 22:16:08

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b987d18e-d4dd-4ba2-af41-4f2348061022'	System	06 Sep 2020 22:16:08
User entered 'None (1)'	System	06 Sep 2020 22:16:08

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:04', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b987d18e-d4dd-4ba2-af41-4f2348061022'	System	06 Sep 2020 22:16:08
User entered '06 Sep 2020 18:16'	System	06 Sep 2020 22:16:08

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 5'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:44:52', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ea35460c-d40c-47bd-a66c-04bee224967b'	System	07 Sep 2020 22:45:14
User entered 'None (1)'	System	07 Sep 2020 22:45:14

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:44:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ea35460c-d40c-47bd-a66c-04bee224967b'	System	07 Sep 2020 22:45:14
User entered 'No (N)'	System	07 Sep 2020 22:45:14

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ea35460c-d40c-47bd-a66c-04bee224967b'	System	07 Sep 2020 22:45:14
User entered 'No (N)'	System	07 Sep 2020 22:45:14

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:06', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ea35460c-d40c-47bd-a66c-04bee224967b'	System	07 Sep 2020 22:45:14
User entered 'None (1)'	System	07 Sep 2020 22:45:14

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:08', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ea35460c-d40c-47bd-a66c-04bee224967b'	System	07 Sep 2020 22:45:14
User entered '07 Sep 2020 18:45'	System	07 Sep 2020 22:45:14

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 6'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 7'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:13', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b5ee40b6-ce13-454b-a114-a858aec969c4'	System	10 Sep 2020 00:58:36
User entered 'None (1)'	System	10 Sep 2020 00:58:36

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:16', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b5ee40b6-ce13-454b-a114-a858aec969c4'	System	10 Sep 2020 00:58:36
User entered 'No (N)'	System	10 Sep 2020 00:58:36

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:21', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b5ee40b6-ce13-454b-a114-a858aec969c4'	System	10 Sep 2020 00:58:36
User entered 'No (N)'	System	10 Sep 2020 00:58:36

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:27', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b5ee40b6-ce13-454b-a114-a858aec969c4'	System	10 Sep 2020 00:58:36
User entered 'None (1)'	System	10 Sep 2020 00:58:36

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b5ee40b6-ce13-454b-a114-a858aec969c4'	System	10 Sep 2020 00:58:36
User entered '09 Sep 2020 20:58'	System	10 Sep 2020 00:58:36

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:52:58', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered 'None (0)'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:53:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered 'None (0)'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:53:05', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered 'None (0)'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:53:08', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered 'None (0)'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:53:10', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered 'None (0)'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:53:13', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered 'None (0)'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:53:20', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered 'No (N)'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T12:53:24', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5eff1022-3e5a-4f05-a535-9344b8073b72'	System	03 Sep 2020 16:53:28
User entered '03 Sep 2020 12:53'	System	03 Sep 2020 16:53:28

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 12:22'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered 'None (0)'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered 'None (0)'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:45', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered 'None (0)'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:50', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered 'None (0)'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:53', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered 'None (0)'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:18:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered 'None (0)'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:19:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered 'No (N)'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-03T19:19:06', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b9f43c7c-3f4d-44d3-94a5-9fed82fd0964'	System	03 Sep 2020 23:19:09
User entered '03 Sep 2020 19:19'	System	03 Sep 2020 23:19:09

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Sep 2020 15:47'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 2'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:51', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929' User entered 'None (0)'	System	04 Sep 2020 23:48:42
	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:54', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929'	System	04 Sep 2020 23:48:42
User entered 'None (0)'	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:47:58', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929' User entered 'None (0)'	System	04 Sep 2020 23:48:42
	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:48:04', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929' User entered 'None (0)'	System	04 Sep 2020 23:48:42
	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:48:15', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929'	System	04 Sep 2020 23:48:42
User entered 'None (0)'	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:48:19', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929'	System	04 Sep 2020 23:48:42
User entered 'None (0)'	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:48:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929'	System	04 Sep 2020 23:48:42
User entered 'No (N)'	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-04T19:48:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd896fed6-5fb4-42f9-bc0e-2367a4f75929'	System	04 Sep 2020 23:48:42
User entered '04 Sep 2020 19:48'	System	04 Sep 2020 23:48:42

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 3'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:41', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca'	System	06 Sep 2020 02:34:19
User entered 'None (0)'	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca'	System	06 Sep 2020 02:34:19
User entered 'None (0)'	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:51', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca' User entered 'None (0)'	System	06 Sep 2020 02:34:19
	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:33:57', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca' User entered 'None (0)'	System	06 Sep 2020 02:34:19
	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:34:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca' User entered 'None (0)'	System	06 Sep 2020 02:34:19
	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:34:04', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca'	System	06 Sep 2020 02:34:19
User entered 'None (0)'	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:34:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca'	System	06 Sep 2020 02:34:19
User entered 'No (N)'	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-05T22:34:13', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e2740dcb-cb17-4347-a64c-bb1576547dca'	System	06 Sep 2020 02:34:19
User entered '05 Sep 2020 22:34'	System	06 Sep 2020 02:34:19

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 4'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:10', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered 'None (0)'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:13', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered 'None (0)'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:16', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered 'None (0)'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:18', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered 'None (0)'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:22', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered 'None (0)'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered 'None (0)'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:29', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered 'No (N)'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-06T18:16:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f0a0795c-4969-4f9f-afef-31d1a1f10e66'	System	06 Sep 2020 22:16:39
User entered '06 Sep 2020 18:16'	System	06 Sep 2020 22:16:39

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 5'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:14', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered 'None (0)'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:17', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered 'None (0)'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:20', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered 'None (0)'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered 'None (0)'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:27', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered 'None (0)'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:30', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered 'None (0)'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:35', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered 'No (N)'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-07T18:45:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '79331414-032b-4c4a-b57c-e45c087b2527'	System	07 Sep 2020 22:45:43
User entered '07 Sep 2020 18:45'	System	07 Sep 2020 22:45:43

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 6'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 7'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:36', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered 'None (0)'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:39', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered 'None (0)'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:43', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered 'None (0)'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered 'None (0)'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:49', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered 'None (0)'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:58:52', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered 'None (0)'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:59:01', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered 'No (N)'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-09-09T20:59:07', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0a41eac6-de22-4a2e-9f2e-b03feef07240'	System	10 Sep 2020 00:59:12
User entered '09 Sep 2020 20:59'	System	10 Sep 2020 00:59:12

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:47:58

US3622142

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:23:01

US3622142

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:23:01

US3622142

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:23:01

US3622142

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:23:01

US3622142

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:24
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:23:07

US3622142

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	16 Sep 2020 17:23:07

US3622142

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:55:21

US3622142

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:55:21

US3622142

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:55:21

US3622142

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:38:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:55:21

US3622142

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:39:10
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:55:29

US3622142

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	23 Sep 2020 18:55:29

US3622142

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:39:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Sep 2020 14:10:52

US3622142

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:39:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '24 Sep 2020'	Junlin Long (b) (4)	29 Sep 2020 14:10:52

US3622142

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:39:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	29 Sep 2020 14:10:52

US3622142

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:39:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Sep 2020 14:10:52
	(b) (4)	

US3622142

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:39:57
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Sep 2020 14:10:57

US3622142

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	29 Sep 2020 14:10:57

US3622142

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:40:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	01 Oct 2020 13:26:27

US3622142

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:40:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '1 Oct 2020'	Junlin Long (b) (4)	01 Oct 2020 13:26:27

US3622142

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:40:47
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	01 Oct 2020 13:26:27

US3622142

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'VISIT2'	System	01 Oct 2020 13:26:27

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '1 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '08:48'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '1 Oct 2020 08:48'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '98.4' F	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Oral (Oral)'	Junlin Long (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	02 Oct 2020 13:59:18
	(b) (4)	

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '77'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'bpm'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '17'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'breaths/min'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '126'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '86'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '1 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '10:40'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '1 Oct 2020 10:40'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '98.4' F	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Oral (Oral)'	Junlin Long (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	02 Oct 2020 13:59:18
	(b) (4)	

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '68'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'bpm'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '16'	Junlin Long (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'breaths/min'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '134'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '86'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'mmHg'	System	02 Oct 2020 13:59:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:51
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Oct 2020 13:59:43

US3622142

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:41:51
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '1 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 13:59:43

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:00
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:00
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	01 Oct 2020 14:31:45
	(b) (4)	

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:00
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered empty.	Junlin Long (b) (4)	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:00
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '1 Oct 2020'	Junlin Long (b) (4)	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:00
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '10:08'	(b) (4) Junlin Long (b) (4) (b) (4)	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '1 Oct 2020 10:08'	System	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:00
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:00
User entered 'ONCE'	System	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 14:31:45

US3622142

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:15
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Oct 2020 14:00:00

US3622142

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:15
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '1 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 14:00:00

US3622142

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:15
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '09:10'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 14:00:00

US3622142

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '1 Oct 2020 09:10'	System	02 Oct 2020 14:00:00

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:26
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '1 Oct 2020'	Junlin Long (b) (4)	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4) (b) (4)	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:26
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:26
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered '09:14'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered '1 Oct 2020 09:14'	System	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4) (b) (4)	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:26
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:26
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	02 Oct 2020 14:00:14
	(b) (4)	

US3622142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered empty.	System	02 Oct 2020 14:00:14

US3622142

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:42:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:11:06
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Oct 2020 14:00:18

US3622142

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	02 Oct 2020 14:00:18

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:43:53', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0bc04a4e-92f1-44ba-93eb-db7d9691d1cb'	System	01 Oct 2020 14:44:14
User entered 'Yes (Y)'	System	01 Oct 2020 14:44:14

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:04', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0bc04a4e-92f1-44ba-93eb-db7d9691d1cb'	System	01 Oct 2020 14:44:14
User entered '98.4'	System	01 Oct 2020 14:44:14

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0bc04a4e-92f1-44ba-93eb-db7d9691d1cb'	System	01 Oct 2020 14:44:14
User entered 'No (N)'	System	01 Oct 2020 14:44:14

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:12', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0bc04a4e-92f1-44ba-93eb-db7d9691d1cb'	System	01 Oct 2020 14:44:14
User entered '01 Oct 2020 10:44'	System	01 Oct 2020 14:44:14

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 10:28'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 12:58'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:58:29', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7e3bcd0c-ee80-40aa-abc8-4ce1994cb1fb'	System	01 Oct 2020 22:59:04
User entered 'Yes (Y)'	System	01 Oct 2020 22:59:04

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:58:43', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7e3bcd0c-ee80-40aa-abc8-4ce1994cb1fb' User entered '97.5'	System	01 Oct 2020 22:59:04
	System	01 Oct 2020 22:59:04

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:58:49', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7e3bcd0c-ee80-40aa-abc8-4ce1994cb1fb'	System	01 Oct 2020 22:59:04
User entered 'No (N)'	System	01 Oct 2020 22:59:04

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:58:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7e3bcd0c-ee80-40aa-abc8-4ce1994cb1fb'	System	01 Oct 2020 22:59:04
User entered '01 Oct 2020 18:58'	System	01 Oct 2020 22:59:04

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 13:53'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 2'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:08', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0491ac9d-d93e-4466-94d6-4f2a06816894'	System	02 Oct 2020 16:23:33
User entered 'Yes (Y)'	System	02 Oct 2020 16:23:33

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:18', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0491ac9d-d93e-4466-94d6-4f2a06816894'	System	02 Oct 2020 16:23:33
User entered '97.6'	System	02 Oct 2020 16:23:33

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:23', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0491ac9d-d93e-4466-94d6-4f2a06816894'	System	02 Oct 2020 16:23:33
User entered 'No (N)'	System	02 Oct 2020 16:23:33

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0491ac9d-d93e-4466-94d6-4f2a06816894'	System	02 Oct 2020 16:23:33
User entered '02 Oct 2020 12:23'	System	02 Oct 2020 16:23:33

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 3'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:10:40', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0d1d2b73-e97e-4794-86b7-c8adcb1028d9'	System	03 Oct 2020 16:11:05
User entered 'Yes (Y)'	System	03 Oct 2020 16:11:05

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:10:51', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0d1d2b73-e97e-4794-86b7-c8adcb1028d9'	System	03 Oct 2020 16:11:05
User entered '97.8'	System	03 Oct 2020 16:11:05

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:10:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0d1d2b73-e97e-4794-86b7-c8adcb1028d9'	System	03 Oct 2020 16:11:05
User entered 'No (N)'	System	03 Oct 2020 16:11:05

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0d1d2b73-e97e-4794-86b7-c8adcb1028d9'	System	03 Oct 2020 16:11:05
User entered '03 Oct 2020 12:11'	System	03 Oct 2020 16:11:05

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 4'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:03:17', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7b3f7f30-9d51-4c44-927d-2d8c33c522eb'	System	04 Oct 2020 21:03:43
User entered 'Yes (Y)'	System	04 Oct 2020 21:03:43

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:03:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7b3f7f30-9d51-4c44-927d-2d8c33c522eb'	System	04 Oct 2020 21:03:43
User entered '97.6'	System	04 Oct 2020 21:03:43

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:03:29', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7b3f7f30-9d51-4c44-927d-2d8c33c522eb'	System	04 Oct 2020 21:03:43
User entered 'No (N)'	System	04 Oct 2020 21:03:43

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:03:39', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '7b3f7f30-9d51-4c44-927d-2d8c33c522eb'	System	04 Oct 2020 21:03:43
User entered '04 Oct 2020 17:03'	System	04 Oct 2020 21:03:43

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 5'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:01', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2cfe52ed-5184-461d-a09a-4c72a0c0f4c9'	System	05 Oct 2020 17:46:29
User entered 'Yes (Y)'	System	05 Oct 2020 17:46:29

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:15', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2cfe52ed-5184-461d-a09a-4c72a0c0f4c9'	System	05 Oct 2020 17:46:29
User entered '97.0'	System	05 Oct 2020 17:46:29

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:20', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2cfe52ed-5184-461d-a09a-4c72a0c0f4c9'	System	05 Oct 2020 17:46:29
User entered 'No (N)'	System	05 Oct 2020 17:46:29

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:23', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '2cfe52ed-5184-461d-a09a-4c72a0c0f4c9'	System	05 Oct 2020 17:46:29
User entered '05 Oct 2020 13:46'	System	05 Oct 2020 17:46:29

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 6'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:11:30', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '504ff78b-30c9-4f5d-b796-0e3eb75fef2e'	System	06 Oct 2020 16:11:55
User entered 'Yes (Y)'	System	06 Oct 2020 16:11:55

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:11:40', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '504ff78b-30c9-4f5d-b796-0e3eb75fef2e' User entered '97.0'	System	06 Oct 2020 16:11:55
	System	06 Oct 2020 16:11:55

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:11:45', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '504ff78b-30c9-4f5d-b796-0e3eb75fef2e'	System	06 Oct 2020 16:11:55
User entered 'No (N)'	System	06 Oct 2020 16:11:55

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:11:51', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '504ff78b-30c9-4f5d-b796-0e3eb75fef2e'	System	06 Oct 2020 16:11:55
User entered '06 Oct 2020 12:11'	System	06 Oct 2020 16:11:55

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 7'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:12', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5231c1f0-314a-48c9-8e78-042037c4141e'	System	08 Oct 2020 04:45:34
User entered 'Yes (Y)'	System	08 Oct 2020 04:45:34

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:22', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5231c1f0-314a-48c9-8e78-042037c4141e' User entered '97.5'	System	08 Oct 2020 04:45:34

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:27', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5231c1f0-314a-48c9-8e78-042037c4141e'	System	08 Oct 2020 04:45:34
User entered 'No (N)'	System	08 Oct 2020 04:45:34

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '5231c1f0-314a-48c9-8e78-042037c4141e'	System	08 Oct 2020 04:45:34
User entered '08 Oct 2020 00:45'	System	08 Oct 2020 04:45:34

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:27', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c4a75554-a19e-48f0-8e1d-bfcf80ef0936'	System	01 Oct 2020 14:44:42
User entered 'None (1)'	System	01 Oct 2020 14:44:42

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c4a75554-a19e-48f0-8e1d-bfcf80ef0936'	System	01 Oct 2020 14:44:42
User entered 'No (N)'	System	01 Oct 2020 14:44:42

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:35', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c4a75554-a19e-48f0-8e1d-bfcf80ef0936'	System	01 Oct 2020 14:44:42
User entered 'No (N)'	System	01 Oct 2020 14:44:42

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c4a75554-a19e-48f0-8e1d-bfcf80ef0936'	System	01 Oct 2020 14:44:42
User entered 'None (1)'	System	01 Oct 2020 14:44:42

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:40', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c4a75554-a19e-48f0-8e1d-bfcf80ef0936'	System	01 Oct 2020 14:44:42
User entered '01 Oct 2020 10:44'	System	01 Oct 2020 14:44:42

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 10:28'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 12:58'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:12', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b6a9ca9a-52b8-433b-a06d-81dd3d4f8257'	System	01 Oct 2020 22:59:31
User entered 'None (1)'	System	01 Oct 2020 22:59:31

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:16', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b6a9ca9a-52b8-433b-a06d-81dd3d4f8257'	System	01 Oct 2020 22:59:31
User entered 'No (N)'	System	01 Oct 2020 22:59:31

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:20', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b6a9ca9a-52b8-433b-a06d-81dd3d4f8257'	System	01 Oct 2020 22:59:31
User entered 'No (N)'	System	01 Oct 2020 22:59:31

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:24', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b6a9ca9a-52b8-433b-a06d-81dd3d4f8257'	System	01 Oct 2020 22:59:31
User entered 'None (1)'	System	01 Oct 2020 22:59:31

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:27', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'b6a9ca9a-52b8-433b-a06d-81dd3d4f8257'	System	01 Oct 2020 22:59:31
User entered '01 Oct 2020 18:59'	System	01 Oct 2020 22:59:31

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 13:53'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 2'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd57cd1c8-4703-4d00-841a-9d8158b4e620'	System	02 Oct 2020 16:23:59
User entered 'None (1)'	System	02 Oct 2020 16:23:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:42', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd57cd1c8-4703-4d00-841a-9d8158b4e620'	System	02 Oct 2020 16:23:59
User entered 'No (N)'	System	02 Oct 2020 16:23:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd57cd1c8-4703-4d00-841a-9d8158b4e620'	System	02 Oct 2020 16:23:59
User entered 'No (N)'	System	02 Oct 2020 16:23:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:50', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd57cd1c8-4703-4d00-841a-9d8158b4e620'	System	02 Oct 2020 16:23:59
User entered 'None (1)'	System	02 Oct 2020 16:23:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:23:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'd57cd1c8-4703-4d00-841a-9d8158b4e620'	System	02 Oct 2020 16:23:59
User entered '02 Oct 2020 12:23'	System	02 Oct 2020 16:23:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 3'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c1d37923-db6e-4cfa-885b-ec99fdbfb4e6'	System	03 Oct 2020 16:11:44
User entered 'None (1)'	System	03 Oct 2020 16:11:44

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:13', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c1d37923-db6e-4cfa-885b-ec99fdbfb4e6'	System	03 Oct 2020 16:11:44
User entered 'No (N)'	System	03 Oct 2020 16:11:44

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:17', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c1d37923-db6e-4cfa-885b-ec99fdbfb4e6'	System	03 Oct 2020 16:11:44
User entered 'No (N)'	System	03 Oct 2020 16:11:44

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c1d37923-db6e-4cfa-885b-ec99fdbfb4e6'	System	03 Oct 2020 16:11:44
User entered 'None (1)'	System	03 Oct 2020 16:11:44

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:41', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c1d37923-db6e-4cfa-885b-ec99fdbfb4e6'	System	03 Oct 2020 16:11:44
User entered '03 Oct 2020 12:11'	System	03 Oct 2020 16:11:44

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 4'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:03:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ece6df7b-5f4f-4020-b5ee-62349da7d82a'	System	04 Oct 2020 21:04:14
User entered 'None (1)'	System	04 Oct 2020 21:04:14

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:03:53', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ece6df7b-5f4f-4020-b5ee-62349da7d82a'	System	04 Oct 2020 21:04:14
User entered 'No (N)'	System	04 Oct 2020 21:04:14

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:03:57', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ece6df7b-5f4f-4020-b5ee-62349da7d82a'	System	04 Oct 2020 21:04:14
User entered 'No (N)'	System	04 Oct 2020 21:04:14

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:01', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ece6df7b-5f4f-4020-b5ee-62349da7d82a'	System	04 Oct 2020 21:04:14
User entered 'None (1)'	System	04 Oct 2020 21:04:14

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ece6df7b-5f4f-4020-b5ee-62349da7d82a'	System	04 Oct 2020 21:04:14
User entered '04 Oct 2020 17:04'	System	04 Oct 2020 21:04:14

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 5'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:29', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a85c0e02-17fd-491f-9705-3ab409e23a3f'	System	05 Oct 2020 17:46:47
User entered 'None (1)'	System	05 Oct 2020 17:46:47

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:32', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a85c0e02-17fd-491f-9705-3ab409e23a3f'	System	05 Oct 2020 17:46:47
User entered 'No (N)'	System	05 Oct 2020 17:46:47

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:37', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a85c0e02-17fd-491f-9705-3ab409e23a3f'	System	05 Oct 2020 17:46:47
User entered 'No (N)'	System	05 Oct 2020 17:46:47

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:42', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a85c0e02-17fd-491f-9705-3ab409e23a3f'	System	05 Oct 2020 17:46:47
User entered 'None (1)'	System	05 Oct 2020 17:46:47

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:45', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a85c0e02-17fd-491f-9705-3ab409e23a3f'	System	05 Oct 2020 17:46:47
User entered '05 Oct 2020 13:46'	System	05 Oct 2020 17:46:47

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 6'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:11:57', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'dcf86e4f-e1eb-4176-a941-682e8f65ea33'	System	06 Oct 2020 16:12:19
User entered 'None (1)'	System	06 Oct 2020 16:12:19

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:01', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'dcf86e4f-e1eb-4176-a941-682e8f65ea33'	System	06 Oct 2020 16:12:19
User entered 'No (N)'	System	06 Oct 2020 16:12:19

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:05', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'dcf86e4f-e1eb-4176-a941-682e8f65ea33'	System	06 Oct 2020 16:12:19
User entered 'No (N)'	System	06 Oct 2020 16:12:19

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'dcf86e4f-e1eb-4176-a941-682e8f65ea33'	System	06 Oct 2020 16:12:19
User entered 'None (1)'	System	06 Oct 2020 16:12:19

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:16', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'dcf86e4f-e1eb-4176-a941-682e8f65ea33'	System	06 Oct 2020 16:12:19
User entered '06 Oct 2020 12:12'	System	06 Oct 2020 16:12:19

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 7'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:39', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ac43cf83-dac8-4e69-b324-e1abc22d7249'	System	08 Oct 2020 04:45:59
User entered 'None (1)'	System	08 Oct 2020 04:45:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:43', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ac43cf83-dac8-4e69-b324-e1abc22d7249'	System	08 Oct 2020 04:45:59
User entered 'No (N)'	System	08 Oct 2020 04:45:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:47', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ac43cf83-dac8-4e69-b324-e1abc22d7249'	System	08 Oct 2020 04:45:59
User entered 'No (N)'	System	08 Oct 2020 04:45:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:52', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ac43cf83-dac8-4e69-b324-e1abc22d7249'	System	08 Oct 2020 04:45:59
User entered 'None (1)'	System	08 Oct 2020 04:45:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:45:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ac43cf83-dac8-4e69-b324-e1abc22d7249'	System	08 Oct 2020 04:45:59
User entered '08 Oct 2020 00:45'	System	08 Oct 2020 04:45:59

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered 'None (0)'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:52', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered 'None (0)'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:54', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered 'None (0)'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:57', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered 'None (0)'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:44:59', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered 'None (0)'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:45:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered 'None (0)'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:45:06', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered 'No (N)'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T10:45:12', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '91e39772-17a6-4a8a-88df-41d353c6b0bb'	System	01 Oct 2020 14:45:15
User entered '01 Oct 2020 10:45'	System	01 Oct 2020 14:45:15

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 10:28'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 12:58'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:34', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered 'None (0)'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:37', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered 'None (0)'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:43', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered 'None (0)'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:48', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered 'None (0)'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:52', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered 'None (0)'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T18:59:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered 'None (0)'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T19:00:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered 'No (N)'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-01T19:00:03', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'fa131ec5-493e-4632-a26a-efba23364f72'	System	01 Oct 2020 23:00:06
User entered '01 Oct 2020 19:00'	System	01 Oct 2020 23:00:06

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '01 Oct 2020 13:53'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 2'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered 'None (0)'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:05', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered 'None (0)'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:08', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered 'None (0)'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:11', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered 'None (0)'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:14', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered 'None (0)'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:17', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered 'None (0)'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:21', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered 'No (N)'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-02T12:24:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '0fd26b12-7ca2-4264-bc3b-b4b869d8c193'	System	02 Oct 2020 16:24:28
User entered '02 Oct 2020 12:24'	System	02 Oct 2020 16:24:28

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 3'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:49', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered 'None (0)'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:53', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered 'None (0)'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:11:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered 'None (0)'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:12:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered 'None (0)'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:12:03', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered 'None (0)'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:12:07', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered 'None (0)'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:12:11', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered 'No (N)'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-03T12:12:21', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '969f61bd-c0ca-44d8-8d3d-d2c02a47ca74'	System	03 Oct 2020 16:12:24
User entered '03 Oct 2020 12:12'	System	03 Oct 2020 16:12:24

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 4'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:18', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered 'None (0)'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:22', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered 'None (0)'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:31', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered 'None (0)'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:39', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered 'None (0)'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:43', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered 'None (0)'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered 'None (0)'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:04:51', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered 'No (N)'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-04T17:05:03', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e5fe78c8-f583-43b5-9e42-686769ba16cd'	System	04 Oct 2020 21:05:05
User entered '04 Oct 2020 17:05'	System	04 Oct 2020 21:05:05

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 5'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:54', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered 'None (0)'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:46:57', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered 'None (0)'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:47:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered 'None (0)'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:47:05', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered 'None (0)'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:47:08', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered 'None (0)'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:47:12', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered 'None (0)'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:47:16', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered 'No (N)'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-05T13:47:20', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e6063b54-d9f5-4d6e-b350-f9f46d732b30'	System	05 Oct 2020 17:47:26
User entered '05 Oct 2020 13:47'	System	05 Oct 2020 17:47:26

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 6'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:21', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480'	System	06 Oct 2020 16:12:53
User entered 'None (0)'	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:24', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480' User entered 'None (0)'	System	06 Oct 2020 16:12:53
	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:30', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480' User entered 'None (0)'	System	06 Oct 2020 16:12:53
	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:35', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480' User entered 'None (0)'	System	06 Oct 2020 16:12:53
	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480'	System	06 Oct 2020 16:12:53
User entered 'None (0)'	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:42', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480'	System	06 Oct 2020 16:12:53
User entered 'None (0)'	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480'	System	06 Oct 2020 16:12:53
User entered 'No (N)'	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-06T12:12:49', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '72af0251-1798-4b53-b09a-2305900d3480'	System	06 Oct 2020 16:12:53
User entered '06 Oct 2020 12:12'	System	06 Oct 2020 16:12:53

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	01 Oct 2020 14:31:45
User entered 'Day 7'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:06', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered 'None (0)'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered 'None (0)'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:14', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered 'None (0)'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:18', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered 'None (0)'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:22', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered 'None (0)'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered 'None (0)'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:29', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered 'No (N)'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-10-08T00:46:36', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '6ab223fc-ff73-4311-bcff-cec32993b7d8'	System	08 Oct 2020 04:46:40
User entered '08 Oct 2020 00:46'	System	08 Oct 2020 04:46:40

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 14:31:45

US3622142

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 14:31:45

US3622142

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:43:30
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 14:46:54

US3622142

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:43:30
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered '10 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 14:46:54

US3622142

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:43:30
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	15 Oct 2020 14:46:54

US3622142

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:43:30
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 14:46:54

US3622142

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:43:40
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 14:46:59

US3622142

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	15 Oct 2020 14:46:59

US3622142

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:44:11
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered 'Yes (Y)'	Junlin Long	15 Oct 2020 14:47:08

US3622142

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:44:11
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 14:47:08

US3622142

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:44:11
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	15 Oct 2020 14:47:08

US3622142

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:44:11
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	15 Oct 2020 14:47:08
	(b) (4)	

US3622142

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 10:44:22
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:59:43
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 14:47:40

US3622142

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	15 Oct 2020 14:47:40

US3622142

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:42:50
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:54:23
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Oct 2020 17:54:37

US3622142

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:42:50
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:54:23
User entered '22 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Oct 2020 17:54:37

US3622142

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:42:50
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:54:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Oct 2020 17:54:37

US3622142

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:42:50
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:54:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Oct 2020 17:54:37
	(b) (4)	

US3622142

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:43:41
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:54:23
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Oct 2020 17:54:40

US3622142

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	22 Oct 2020 17:54:40

US3622142

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:43:56
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:25

US3622142

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:43:56
User entered '29 Oct 2020'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:25

US3622142

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:43:56
User entered 'Clinic (Clinic)'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:25

US3622142

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User entered 'VISIT3'	System	29 Oct 2020 15:23:25

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered '29 Oct 2020'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered '10:56'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User entered '29 Oct 2020 10:56'	System	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered '98.9' F	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered 'Oral (Oral)'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered empty.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered '95'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User entered 'bpm'	System	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered '20'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User entered 'breaths/min'	System	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered '134'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User entered 'mmHg'	System	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:10
User entered '91'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User entered 'mmHg'	System	29 Oct 2020 15:23:48

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29

US3622142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29

US3622142

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:52

US3622142

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:36
User entered empty.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:23:52

US3622142

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:49
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:24:02

US3622142

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:49
User entered '29 Oct 2020'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:24:02

US3622142

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:49
User entered '11:10'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:24:02

US3622142

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:29
User entered '29 Oct 2020 11:10'	System	29 Oct 2020 15:24:02

US3622142

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:44:57
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:24:05

US3622142

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	29 Oct 2020 15:24:05

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 64'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12
Data entry locked.	System	03 Sep 2020 16:47:58
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:15:12
Data entry locked.	System	03 Sep 2020 16:47:58
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 71'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-11-13T00:29:59', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'da08df7b-8cc2-4981-8f9e-0fab60ab0edd'	System	13 Nov 2020 05:30:15
User entered 'No (N)'	System	13 Nov 2020 05:30:15

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-11-13T00:30:05', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'da08df7b-8cc2-4981-8f9e-0fab60ab0edd'	System	13 Nov 2020 05:30:15
User entered 'No (N)'	System	13 Nov 2020 05:30:15

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-11-13T00:30:11', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'da08df7b-8cc2-4981-8f9e-0fab60ab0edd'	System	13 Nov 2020 05:30:15
User entered '13 Nov 2020 00:30:11'	System	13 Nov 2020 05:30:15

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered 'Day 78'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-11-19T16:02:53', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '3fff8991-f1c1-48d6-a843-eeb53373fe1c'	System	19 Nov 2020 21:03:06
User entered 'No (N)'	System	19 Nov 2020 21:03:06

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-11-19T16:02:58', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '3fff8991-f1c1-48d6-a843-eeb53373fe1c'	System	19 Nov 2020 21:03:06
User entered 'No (N)'	System	19 Nov 2020 21:03:06

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-11-19T16:03:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '3fff8991-f1c1-48d6-a843-eeb53373fe1c'	System	19 Nov 2020 21:03:06
User entered '19 Nov 2020 16:03:02'	System	19 Nov 2020 21:03:06

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 16:47:58

US3622142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:11:34
Data entry locked.	System	03 Sep 2020 16:47:58
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 16:47:58

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2020-11-28T00:02:19', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '58d1af11-f6b9-4905-acec-337ca79d4a35'	System	28 Nov 2020 05:03:20
User entered 'No (N)'	System	28 Nov 2020 05:03:20

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2020-11-28T00:02:23', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '58d1af11-f6b9-4905-acec-337ca79d4a35'	System	28 Nov 2020 05:03:20
User entered 'No (N)'	System	28 Nov 2020 05:03:20

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-11-28T00:02:28', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '58d1af11-f6b9-4905-acec-337ca79d4a35'	System	28 Nov 2020 05:03:20
User entered '28 Nov 2020 00:02:28'	System	28 Nov 2020 05:03:20

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2020-12-08T12:26:56', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bac309e1-da4c-482d-91fa-5b0785a9db3d'	System	08 Dec 2020 17:27:11
User entered 'No (N)'	System	08 Dec 2020 17:27:11

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2020-12-08T12:27:02', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bac309e1-da4c-482d-91fa-5b0785a9db3d'	System	08 Dec 2020 17:27:11
User entered 'No (N)'	System	08 Dec 2020 17:27:11

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-12-08T12:27:06', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bac309e1-da4c-482d-91fa-5b0785a9db3d'	System	08 Dec 2020 17:27:11
User entered '08 Dec 2020 12:27:06'	System	08 Dec 2020 17:27:11

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2020-12-16T11:41:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ee8be816-5c41-4c43-b25d-47b3f1bf189c'	System	16 Dec 2020 16:41:12
User entered 'No (N)'	System	16 Dec 2020 16:41:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2020-12-16T11:41:05', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ee8be816-5c41-4c43-b25d-47b3f1bf189c'	System	16 Dec 2020 16:41:12
User entered 'No (N)'	System	16 Dec 2020 16:41:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-12-16T11:41:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ee8be816-5c41-4c43-b25d-47b3f1bf189c' User entered '16 Dec 2020 11:41:09'	System	16 Dec 2020 16:41:12
	System	16 Dec 2020 16:41:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2020-12-19T00:02:36', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ef955e68-735e-43fb-98e0-8fa7ff03f98d'	System	19 Dec 2020 05:03:27
User entered 'No (N)'	System	19 Dec 2020 05:03:27

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2020-12-19T00:02:45', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ef955e68-735e-43fb-98e0-8fa7ff03f98d'	System	19 Dec 2020 05:03:27
User entered 'No (N)'	System	19 Dec 2020 05:03:27

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-12-19T00:02:52', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'ef955e68-735e-43fb-98e0-8fa7ff03f98d'	System	19 Dec 2020 05:03:27
User entered '19 Dec 2020 00:02:52'	System	19 Dec 2020 05:03:27

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2020-12-29T13:49:37', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e4696035-55ef-464e-a2d1-b6feb3366961'	System	29 Dec 2020 18:49:48
User entered 'No (N)'	System	29 Dec 2020 18:49:48

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2020-12-29T13:49:41', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e4696035-55ef-464e-a2d1-b6feb3366961'	System	29 Dec 2020 18:49:48
User entered 'No (N)'	System	29 Dec 2020 18:49:48

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2020-12-29T13:49:45', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e4696035-55ef-464e-a2d1-b6feb3366961'	System	29 Dec 2020 18:49:48
User entered '29 Dec 2020 13:49:45'	System	29 Dec 2020 18:49:48

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-01-02T00:02:17', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '3763920b-3674-4af4-846e-8dafc80acb1e'	System	02 Jan 2021 05:02:59
User entered 'No (N)'	System	02 Jan 2021 05:02:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-01-02T00:02:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '3763920b-3674-4af4-846e-8dafc80acb1e'	System	02 Jan 2021 05:02:59
User entered 'No (N)'	System	02 Jan 2021 05:02:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-01-02T00:02:30', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '3763920b-3674-4af4-846e-8dafc80acb1e' User entered '02 Jan 2021 00:02:30'	System	02 Jan 2021 05:02:59
	System	02 Jan 2021 05:02:59

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-01-13T14:30:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f33a8510-dcfd-42fe-a697-cf5eb7f8abc5'	System	13 Jan 2021 19:30:51
User entered 'No (N)'	System	13 Jan 2021 19:30:51

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-01-13T14:30:42', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f33a8510-dcfd-42fe-a697-cf5eb7f8abc5'	System	13 Jan 2021 19:30:51
User entered 'No (N)'	System	13 Jan 2021 19:30:51

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-01-13T14:30:47', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'f33a8510-dcfd-42fe-a697-cf5eb7f8abc5'	System	13 Jan 2021 19:30:51
User entered '13 Jan 2021 14:30:47'	System	13 Jan 2021 19:30:51

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-01-17T11:48:46', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '32097961-e2c1-4b70-a54c-253e3b7868f0'	System	17 Jan 2021 16:48:56
User entered 'No (N)'	System	17 Jan 2021 16:48:56

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-01-17T11:48:50', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '32097961-e2c1-4b70-a54c-253e3b7868f0'	System	17 Jan 2021 16:48:56
User entered 'No (N)'	System	17 Jan 2021 16:48:56

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-01-17T11:48:54', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '32097961-e2c1-4b70-a54c-253e3b7868f0' User entered '17 Jan 2021 11:48:54'	System	17 Jan 2021 16:48:56

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-01-24T16:28:16', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bda89fe1-01d3-4425-aa64-d86820aebb78'	System	24 Jan 2021 21:28:35
User entered 'No (N)'	System	24 Jan 2021 21:28:35

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-01-24T16:28:25', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bda89fe1-01d3-4425-aa64-d86820aebb78'	System	24 Jan 2021 21:28:35
User entered 'No (N)'	System	24 Jan 2021 21:28:35

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-01-24T16:28:28', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bda89fe1-01d3-4425-aa64-d86820aebb78'	System	24 Jan 2021 21:28:35
User entered '24 Jan 2021 16:28:28'	System	24 Jan 2021 21:28:35

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-02T03:27:30', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered 'Yes (Y)'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-02-02T03:27:41', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered 'Yes (Y)'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Please 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 (4d63fb4d0e543563)', Time: '2021-02-02T03:27:59', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-02T03:28:09', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered 'Yes (Y)'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca' User entered '1'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '1'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '1'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '1'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca' User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca' User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca' User entered '1'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '1'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '1'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:28:33', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '0'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Please 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 (4d63fb4d0e543563)', Time: '2021-02-02T03:28:40', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-02T03:28:50', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered 'Yes (Y)'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Please 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 (4d63fb4d0e543563)', Time: '2021-02-02T03:29:01', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-02T03:29:47', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '96d83149-6006-47d0-a046-9d3618e776ca'	System	02 Feb 2021 08:29:57
User entered '02 Feb 2021 03:29:47'	System	02 Feb 2021 08:29:57

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-06T00:02:14', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a5399060-a8ee-433e-9a22-8a67b8a4c638'	System	06 Feb 2021 05:03:39
User entered 'No (N)'	System	06 Feb 2021 05:03:39

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-02-06T00:02:41', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a5399060-a8ee-433e-9a22-8a67b8a4c638'	System	06 Feb 2021 05:03:39
User entered 'No (N)'	System	06 Feb 2021 05:03:39

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-06T00:02:49', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'a5399060-a8ee-433e-9a22-8a67b8a4c638'	System	06 Feb 2021 05:03:39
User entered '06 Feb 2021 00:02:49'	System	06 Feb 2021 05:03:39

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-17T12:33:26', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '80db82bc-4c6b-4b34-9acc-8315e6c58cda'	System	17 Feb 2021 17:33:54
User entered 'Yes (Y)'	System	17 Feb 2021 17:33:54

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-02-17T12:33:32', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '80db82bc-4c6b-4b34-9acc-8315e6c58cda'	System	17 Feb 2021 17:33:54
User entered 'No (N)'	System	17 Feb 2021 17:33:54

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-17T12:33:38', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '80db82bc-4c6b-4b34-9acc-8315e6c58cda'	System	17 Feb 2021 17:33:54
User entered 'No (N)'	System	17 Feb 2021 17:33:54

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-17T12:33:45', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '80db82bc-4c6b-4b34-9acc-8315e6c58cda'	System	17 Feb 2021 17:33:54
User entered 'No (N)'	System	17 Feb 2021 17:33:54

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-17T12:33:50', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '80db82bc-4c6b-4b34-9acc-8315e6c58cda'	System	17 Feb 2021 17:33:54
User entered '17 Feb 2021 12:33:50'	System	17 Feb 2021 17:33:54

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-02-24T08:03:11-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e9242e53-7d4f-47d0-af98-45f2fc3571a5'	System	24 Feb 2021 13:03:31
User entered 'No (N)'	System	24 Feb 2021 13:03:31

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-02-24T08:03:19-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e9242e53-7d4f-47d0-af98-45f2fc3571a5'	System	24 Feb 2021 13:03:31
User entered 'No (N)'	System	24 Feb 2021 13:03:31

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-02-24T08:03:23-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'e9242e53-7d4f-47d0-af98-45f2fc3571a5' User entered '24 Feb 2021 08:03:23'	System	24 Feb 2021 13:03:31
	System	24 Feb 2021 13:03:31

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-03-02T15:03:33-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '507a224a-536d-4f4e-8e42-9fa9d51eb8a9'	System	02 Mar 2021 20:03:53
User entered 'No (N)'	System	02 Mar 2021 20:03:53

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-03-02T15:03:37-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '507a224a-536d-4f4e-8e42-9fa9d51eb8a9'	System	02 Mar 2021 20:03:53
User entered 'No (N)'	System	02 Mar 2021 20:03:53

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-03-02T15:03:40-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '507a224a-536d-4f4e-8e42-9fa9d51eb8a9'	System	02 Mar 2021 20:03:53
User entered '02 Mar 2021 15:03:40'	System	02 Mar 2021 20:03:53

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-03-10T08:52:50-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '442f24a6-1227-46e5-b4bc-063b467ec533'	System	10 Mar 2021 13:53:02
User entered 'No (N)'	System	10 Mar 2021 13:53:02

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-03-10T08:52:54-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '442f24a6-1227-46e5-b4bc-063b467ec533'	System	10 Mar 2021 13:53:02
User entered 'No (N)'	System	10 Mar 2021 13:53:02

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-03-10T08:52:58-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '442f24a6-1227-46e5-b4bc-063b467ec533'	System	10 Mar 2021 13:53:02
User entered '10 Mar 2021 08:52:58'	System	10 Mar 2021 13:53:02

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-03-15T22:27:22-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '26990473-8a6b-407c-87d5-097a0a5e9c1f'	System	16 Mar 2021 02:27:36
User entered 'No (N)'	System	16 Mar 2021 02:27:36

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-03-15T22:27:29-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '26990473-8a6b-407c-87d5-097a0a5e9c1f'	System	16 Mar 2021 02:27:36
User entered 'No (N)'	System	16 Mar 2021 02:27:36

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-03-15T22:27:32-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '26990473-8a6b-407c-87d5-097a0a5e9c1f' User entered '15 Mar 2021 22:27:32'	System	16 Mar 2021 02:27:36
	System	16 Mar 2021 02:27:36

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-03-20T22:53:41-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '462fb297-14cb-4e75-885f-d98e6eb68305'	System	21 Mar 2021 02:54:45
User entered 'No (N)'	System	21 Mar 2021 02:54:45

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-03-20T22:53:47-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '462fb297-14cb-4e75-885f-d98e6eb68305'	System	21 Mar 2021 02:54:45
User entered 'No (N)'	System	21 Mar 2021 02:54:45

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-03-20T22:53:51-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '462fb297-14cb-4e75-885f-d98e6eb68305'	System	21 Mar 2021 02:54:45
User entered '20 Mar 2021 22:53:51'	System	21 Mar 2021 02:54:45

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-03-31T08:51:28-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bdc9b5bd-51df-425c-8ac9-b9ae02204cb6'	System	31 Mar 2021 12:51:41
User entered 'No (N)'	System	31 Mar 2021 12:51:41

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-03-31T08:51:32-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bdc9b5bd-51df-425c-8ac9-b9ae02204cb6'	System	31 Mar 2021 12:51:41
User entered 'No (N)'	System	31 Mar 2021 12:51:41

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-03-31T08:51:36-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bdc9b5bd-51df-425c-8ac9-b9ae02204cb6' User entered '31 Mar 2021 08:51:36'	System	31 Mar 2021 12:51:41
	System	31 Mar 2021 12:51:41

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-04-03T00:08:19-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bd33f3f5-74cc-4873-94eb-41ca08dbfb89'	System	03 Apr 2021 04:08:40
User entered 'No (N)'	System	03 Apr 2021 04:08:40

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-04-03T00:08:27-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bd33f3f5-74cc-4873-94eb-41ca08dbfb89'	System	03 Apr 2021 04:08:40
User entered 'No (N)'	System	03 Apr 2021 04:08:40

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-04-03T00:08:33-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'bd33f3f5-74cc-4873-94eb-41ca08dbfb89'	System	03 Apr 2021 04:08:40
User entered '03 Apr 2021 00:08:33'	System	03 Apr 2021 04:08:40

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-04-10T00:02:15-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '41916352-1a8b-4b1a-a779-1c66d5773abb' User entered 'No (N)'	System	10 Apr 2021 04:05:17

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-04-10T00:02:20-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '41916352-1a8b-4b1a-a779-1c66d5773abb' User entered 'No (N)'	System	10 Apr 2021 04:05:17

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-04-10T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '41916352-1a8b-4b1a-a779-1c66d5773abb' User entered '10 Apr 2021 00:02:26'	System	10 Apr 2021 04:05:17
	System	10 Apr 2021 04:05:17

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-04-19T21:02:21-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '99491a56-4adb-4939-bfc3-13432aa43842'	System	20 Apr 2021 01:07:42
User entered 'No (N)'	System	20 Apr 2021 01:07:42

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-04-19T21:02:26-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '99491a56-4adb-4939-bfc3-13432aa43842'	System	20 Apr 2021 01:07:42
User entered 'No (N)'	System	20 Apr 2021 01:07:42

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-04-19T21:02:29-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '99491a56-4adb-4939-bfc3-13432aa43842' User entered '19 Apr 2021 21:02:29'	System	20 Apr 2021 01:07:42
	System	20 Apr 2021 01:07:42

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-04-25T11:40:14-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '18bcadb9-abb5-4f4f-b7bb-835a698236af' User entered 'No (N)'	System	25 Apr 2021 15:40:25
	System	25 Apr 2021 15:40:25

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-04-25T11:40:17-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '18bcadb9-abb5-4f4f-b7bb-835a698236af'	System	25 Apr 2021 15:40:25
User entered 'No (N)'	System	25 Apr 2021 15:40:25

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-04-25T11:40:21-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: '18bcadb9-abb5-4f4f-b7bb-835a698236af' User entered '25 Apr 2021 11:40:21'	System	25 Apr 2021 15:40:25
	System	25 Apr 2021 15:40:25

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[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 (4d63fb4d0e543563)', Time: '2021-05-01T20:32:39-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c72d8b92-2a01-44b9-b1c6-796eeec4863'	System	02 May 2021 00:32:56
User entered 'No (N)'	System	02 May 2021 00:32:56

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Have you been exposed to someone with 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 (4d63fb4d0e543563)', Time: '2021-05-01T20:32:47-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c72d8b92-2a01-44b9-b1c6-796eeec4863'	System	02 May 2021 00:32:56
User entered 'No (N)'	System	02 May 2021 00:32:56

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-05-01T20:32:53-04:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c72d8b92-2a01-44b9-b1c6-796eeec4863'	System	02 May 2021 00:32:56
User entered '01 May 2021 20:32:53'	System	02 May 2021 00:32:56

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:15:12

US3622142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:15:12
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:15:12

US3622142

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:11:43

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)	25 Apr 2021 11:46:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-03-02T15:03:54-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c3a62b9a-b22c-426e-810d-638eb3886709'	System	02 Mar 2021 20:04:12
User entered 'No (N)'	System	02 Mar 2021 20:04:12

US3622142

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:11:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:46:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d63fb4d0e543563)', Time: '2021-03-02T15:04:03-05:00', User OID: 'PatientReportedOutcome (US3622142)', ODM File OID: 'c3a62b9a-b22c-426e-810d-638eb3886709'	System	02 Mar 2021 20:04:12
User entered '02 Mar 2021 15:04:03'	System	02 Mar 2021 20:04:12

US3622142

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 12:17:45
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 12:54:15

US3622142

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 12:17:45
User entered '25 Nov 2020'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 12:54:15

US3622142

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 12:17:45
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 12:54:15

US3622142

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 12:17:45
User entered empty.	Junlin Long (b) (4) (b) (4)	30 Nov 2020 12:54:15

US3622142

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 12:17:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	30 Nov 2020 12:54:18

US3622142

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:54:28
User entered 'I'	System	30 Nov 2020 12:54:18

US3622142

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Dec 2020 19:00:00

US3622142

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
User entered '29 Dec 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Dec 2020 19:00:00

US3622142

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Dec 2020 19:00:00

US3622142

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Dec 2020 19:00:00
	(b) (4)	

US3622142

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Dec 2020 19:00:05

US3622142

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
User entered 'I'	System	29 Dec 2020 19:00:05

US3622142

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:14
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Jan 2021 16:09:42

US3622142

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:14
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '28 Jan 2021'	Junlin Long (b) (4)	28 Jan 2021 16:09:42

US3622142

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:14
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	28 Jan 2021 16:09:42

US3622142

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:14
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	28 Jan 2021 16:09:42
	(b) (4)	

US3622142

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:24
User closed query 'Please enter Day 179 Safety call' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:49:43
Query 'Please enter Day 179 Safety call' answered with 'entered' (Site from CRA).	Junlin Long (b) (4)	26 Mar 2021 14:42:37
User opened query 'Please enter Day 179 Safety call' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 13:59:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Jan 2021 16:09:46

US3622142

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
User entered 'I'	System	28 Jan 2021 16:09:46

US3622142

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Mar 2021 14:42:14

US3622142

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '26 Feb 2021'	Junlin Long (b) (4)	26 Mar 2021 14:42:14

US3622142

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Mar 2021 14:42:14

US3622142

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Mar 2021 14:42:14
	(b) (4)	

US3622142

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:59:46
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Mar 2021 14:42:17

US3622142

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 13:25:55
User entered 'I'	System	26 Mar 2021 14:42:17

US3622142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:15:08
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Apr 2021 15:57:33
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:15:08
User entered '7 Apr 2021'	Junlin Long (b) (4)	07 Apr 2021 15:57:33
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:15:08
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	07 Apr 2021 15:57:33
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered 'VISIT4'	System	07 Apr 2021 15:57:33

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered '7 Apr 2021'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered '10:30'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered '7 Apr 2021 10:30'	System	07 Apr 2021 15:57:54

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered '97.7' F	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered 'Oral (Oral)'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered empty.	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered '75'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered 'bpm'	System	07 Apr 2021 15:57:54

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered '16'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered 'breaths/min'	System	07 Apr 2021 15:57:54

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered '134'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered 'mmHg'	System	07 Apr 2021 15:57:54

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:16
User entered '83'	Junlin Long (b) (4)	07 Apr 2021 15:57:54
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered 'mmHg'	System	07 Apr 2021 15:57:54

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37

US3622142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37

US3622142

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:28
User entered 'No (N)'	Junlin Long (b) (4)	07 Apr 2021 15:57:57
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:28
User entered empty.	Junlin Long (b) (4)	07 Apr 2021 15:57:57
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:36
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Apr 2021 15:58:05
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:36
User entered '7 Apr 2021'	Junlin Long (b) (4)	07 Apr 2021 15:58:05
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:36
User entered '10:40'	Junlin Long (b) (4)	07 Apr 2021 15:58:05
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered '7 Apr 2021 10:40'	System	07 Apr 2021 15:58:05

US3622142

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:55:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:16:47
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Apr 2021 15:58:09
	(b) (4)	

US3622142

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:37
User entered 'I'	System	07 Apr 2021 15:58:09

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:43

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:31:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '2 Feb 2021'	Junlin Long (b) (4)	04 Feb 2021 16:34:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:43

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:31:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '10:00'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:43

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:31:54
User entered '2 Feb 2021 10:00'	System	04 Feb 2021 16:34:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:43

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:31:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Safety Call (Safety Call)'	Junlin Long (b) (4)	04 Feb 2021 16:34:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:43

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:31:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Feb 2021 16:34:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 1 (Day 1)'	Junlin Long	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '26 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Moderate (Moderate)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:34:52

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 2 (Day 2)'	Junlin Long	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '27 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Moderate (Moderate)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:12

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 3 (Day 3)'	Junlin Long	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '28 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Moderate (Moderate)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:35:37

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 4 (Day 4)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:10
User closed query 'Per ETRTR: O2 saturation is recorded as '88%' in COVID-19 severity assessment page. Kindly mention the value. Thank You! ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 13:44:02
Query 'Per ETRTR: O2 saturation is recorded as '88%' in COVID-19 severity assessment page. Kindly mention the value. Thank You! ' answered with 'covid-19 severity assessment page updated; o2 saturation here updated' (Site from CRA).	Junlin Long (b) (4) (b) (4)	25 Feb 2021 13:05:55
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 13:05:18
User entered '90' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	25 Feb 2021 13:05:18
User opened query 'Per ETRTR: O2 saturation is recorded as '88%' in COVID-19 severity assessment page. Kindly mention the value. Thank You! ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 11:21:30
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Severe (Severe)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:36:14

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 5 (Day 5)'	Junlin Long	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '30 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Severe (Severe)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:36:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 6 (Day 6)'	Junlin Long	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Severe (Severe)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:08

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 7 (Day 7)'	Junlin Long	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '1 Feb 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Severe (Severe)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:29

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 8 (Day 8)'	Junlin Long	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '2 Feb 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Severe (Severe)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:37:54

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Day 9 (Day 9)'	Junlin Long	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '3 Feb 2021'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
Signature has been broken.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:12:20
User entered '95' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:12:20
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '94'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '98.5' F	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Mild (Mild)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Moderate (Moderate)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'None (None)'	Junlin Long (b) (4)	04 Feb 2021 16:38:27

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '95'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:14:28
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 13:12:20

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '96'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '98' F	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:15:39

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '95'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	18 Feb 2021 13:20:18
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 13:20:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Feb 2021 13:16:31
User entered '98.7' (non-conformant).	(b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:31

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'l'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered empty.	System	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:56

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'l'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered empty.	System	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:24

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'l'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered empty.	System	18 Feb 2021 13:17:51

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:17:51

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '95'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:18:36

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '94'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '98' F	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:19:35

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '95'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
User entered '%'	System	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:11:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:44:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:20:04

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered '2 Feb 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 04:05:21
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed positive test result on 29JAN2021; covid-19 entered in ae form' (Site from System).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:06:56
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Feb 2021 18:05:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-JAN-2021 is recorded under Covid-19 Assessment visit in EDC, however, swab sample swab sample for 29-JAN-2021 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date, else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:50:46
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-JAN-2021 is recorded under Covid-19 Assessment visit in EDC, however, swab sample swab sample for 29-JAN-2021 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date, else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'It's recorded on this page that participant was tested covid-19 positive at Mount Sinai Hospital on 29JAN2021.' (Site from DM).	Junlin Long (b) (4) (b) (4)	08 Mar 2021 12:29:59
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-JAN-2021 is recorded under Covid-19 Assessment visit in EDC, however, swab sample swab sample for 29-JAN-2021 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date, else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:48:34
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[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)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered 'Mount Sinai Hospital'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:44:43
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:43

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:07
User entered 'I'	System	23 Feb 2021 18:05:25

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered '90' reason for change: New Information	Junlin Long (b) (4) (b) (4)	25 Feb 2021 13:05:07
User entered '88'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

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Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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Generated On: 10 Jun 2021 09:11:43

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

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[End Date](#)

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User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

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Generated On: 10 Jun 2021 09:11:43

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:43

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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Generated On: 10 Jun 2021 09:11:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

US3622142

Folder: Covid-19 Assessment 02 Feb 2021

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:12
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:18:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:11:43

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:32:18
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:45:27
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:19:22

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:11:43

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	18 Feb 2021 14:16:14

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:11:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:16:14

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:16:14

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:11:43

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	18 Feb 2021 14:25:47

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:11:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:25:47

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:25:47

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:11:43

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	18 Feb 2021 14:26:15

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:11:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:26:15

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:26:15

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:11:43

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Feb 2021 14:26:25

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:11:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:26:25

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:26:25

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:11:43

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	18 Feb 2021 14:26:40

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:11:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:26:40

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:47:44
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:26:40

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:11:43

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User accepted default value 'Day 21 (Day 21)'	Junlin Long (b) (4)	23 Feb 2021 18:20:34
	(b) (4)	

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:11:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:44
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:20:34

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:44
User entered '18 Feb 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:20:34

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:11:43

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User accepted default value 'Day 28 (Day 28)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:02:26

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:11:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:44
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:02:26

US3622142

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:44
User entered '25 Feb 2021'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:02:26

US3622142

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:57
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:45:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Feb 2021 16:42:16

US3622142

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:57
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:45:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,04,06,11FEB2020 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)	22 Feb 2021 08:23:14
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,04,06,11FEB2020 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 COLLECTION PAGE UPDATED.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:28:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,04,06,11FEB2020 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)	18 Feb 2021 06:30:04
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '2 Feb 2021'	Junlin Long (b) (4)	04 Feb 2021 16:42:16

US3622142

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[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 19:36:57
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:45:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Home (Home)'	Junlin Long (b) (4)	04 Feb 2021 16:42:16

US3622142

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:57
User entered 'SICKD1'	System	04 Feb 2021 16:42:16

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
User entered empty.	System	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 16:42:38
	(b) (4)	
DataPoint set to visible.	System	04 Feb 2021 16:42:16

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 16:42:38
	(b) (4)	
DataPoint set to visible.	System	04 Feb 2021 16:42:16

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
User entered empty.	System	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
User entered empty.	System	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
User entered empty.	System	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06
User entered empty.	System	04 Feb 2021 16:42:38

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 19:37:06

US3622142

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:06

US3622142

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 16:42:42

US3622142

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:42

US3622142

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:11:43

[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 19:37:13
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 16:42:46

US3622142

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:37:13
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:46:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:42:46

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:28
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:46:51
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:06

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:28
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:46:51
User entered '25 Feb 2021'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:06

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:28
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:46:51
User entered 'Clinic (Clinic)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:06

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:28
User entered 'SICKD28'	System	25 Feb 2021 19:01:06

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered '25 Feb 2021'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered '10:23'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User entered '25 Feb 2021 10:23'	System	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered missing code ND - Not Done.	Junlin Long (b) (4)	25 Feb 2021 19:01:40
DataPoint set to visible.	(b) (4) System	25 Feb 2021 19:01:06

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered missing code ND - Not Done.	Junlin Long (b) (4)	25 Feb 2021 19:01:40
DataPoint set to visible.	(b) (4) System	25 Feb 2021 19:01:06

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered '97.9' F	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered 'Oral (Oral)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered '76'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User entered 'bpm'	System	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered '20'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User entered 'breaths/min'	System	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered '137'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User entered 'mmHg'	System	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:00
User entered '82'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39
User entered 'mmHg'	System	25 Feb 2021 19:01:40

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:39

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:46
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:20
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:49

US3622142

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:46
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:20
User entered '25 Feb 2021'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:01:49

US3622142

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:11:43

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:52
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:29
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:02:14

US3622142

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:11:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:52
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:47:29
User entered '25 Feb 2021'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:02:14

US3622142

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:14
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 13:29:05

US3622142

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:14
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 13:29:05

US3622142

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[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 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:14
User closed query 'Please update OLD29 visit' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:48:00
Query 'Please update OLD29 visit' answered with 'participant has not come for OL2-D29 yet.' (Site from CRA).	Junlin Long (b) (4) (b) (4)	26 Mar 2021 14:31:02
User opened query 'Please update OLD29 visit' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:00:43
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	28 Jan 2021 15:08:09
User entered 'Clinic (Clinic)'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 13:29:05

US3622142

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 13:29:05

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	Junlin Long (b) (4)	15 Jan 2021 13:29:16

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) Junlin Long (b) (4)	09 Mar 2021 15:07:47
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:29:59

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 13:29:16

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	Junlin Long (b) (4)	09 Mar 2021 15:07:47
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:29:59

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	Junlin Long (b) (4)	15 Jan 2021 13:29:16

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	15 Jan 2021 13:29:16

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:58:38
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	15 Jan 2021 13:29:16
	(b) (4)	

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:58:38
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	15 Jan 2021 13:29:16
	(b) (4)	

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 13:29:16

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '1'	System	15 Jan 2021 13:29:16

US3622142

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'I'	System	15 Jan 2021 13:29:16

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '62.5' in	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '175' lb	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '31.56370'	System	15 Jan 2021 15:33:30
DataPoint set to visible.	System	15 Jan 2021 13:29:16

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '62.5' in	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '175' lb	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '31.56370'	System	15 Jan 2021 15:33:30
DataPoint set to visible.	System	15 Jan 2021 13:29:16

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '07:48'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '15 Jan 2021 07:48'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '97.7' F	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	15 Jan 2021 15:33:30
	(b) (4)	

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '87'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'bpm'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '20'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'breaths/min'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '149'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'mmHg'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '95'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'mmHg'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '62.5' in	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '175' lb	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '31.56370'	System	15 Jan 2021 15:33:30
DataPoint set to visible.	System	15 Jan 2021 13:29:16

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '08:55'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '15 Jan 2021 08:55'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '98.8' F	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	15 Jan 2021 15:33:30
	(b) (4)	

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '78'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'bpm'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '16'	Junlin Long (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'breaths/min'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '143'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'mmHg'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:31
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '81'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:30

US3622142

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'mmHg'	System	15 Jan 2021 15:33:30

US3622142

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:36
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	Junlin Long (b) (4)	15 Jan 2021 15:33:34

US3622142

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:36
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	15 Jan 2021 15:33:34
	(b) (4)	

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:41
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 13:29:31

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:41
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	15 Jan 2021 13:29:31
	(b) (4)	

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:41
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	Junlin Long (b) (4)	15 Jan 2021 13:29:31

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'mRNA-1273'	System	15 Jan 2021 13:29:31
DataPoint set to visible.	System	15 Jan 2021 13:29:16

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:41
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	Junlin Long (b) (4)	15 Jan 2021 13:29:31

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:41
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '08:23'	Junlin Long (b) (4)	15 Jan 2021 13:29:31

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '15 Jan 2021 08:23'	System	15 Jan 2021 13:29:31

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:41
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	15 Jan 2021 13:29:31

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:41
User entered 'ONCE'	System	15 Jan 2021 13:29:31

US3622142

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 13:29:31

US3622142

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:51
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 15:33:48

US3622142

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:51
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:48

US3622142

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:51
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '07:55'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:48

US3622142

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '15 Jan 2021 07:55'	System	15 Jan 2021 15:33:48

US3622142

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 15:33:57

US3622142

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:57

US3622142

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:12:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '08:00'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Jan 2021 15:33:57

US3622142

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered '15 Jan 2021 08:00'	System	15 Jan 2021 15:33:57

US3622142

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

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 11:13:01
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Jan 2021 15:34:01

US3622142

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

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:03:06
User entered 'I'	System	15 Jan 2021 15:34:01

US3622142

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:35:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:00:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Jan 2021 18:48:19

US3622142

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:35:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:00:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '22 Jan 2021'	Junlin Long (b) (4)	22 Jan 2021 18:48:19

US3622142

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:35:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:00:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:48:19

US3622142

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:35:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:00:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:48:19
	(b) (4)	

US3622142

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:35:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:00:23
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:48:23

US3622142

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:35:55
User entered 'I'	System	22 Jan 2021 18:48:23

US3622142

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:35:55
User entered '1'	System	22 Jan 2021 18:48:23
DataPoint set to visible.	System	22 Jan 2021 18:48:23

US3622142

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	22 Jan 2021 18:48:23

US3622142

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:11:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:05
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:48:44
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:48:44
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:48:44
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	14 Jan 2021 15:04:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 14:27:44
User entered 'No (N)'	(b) (4)	
	Junlin Long (b) (4)	14 Dec 2020 14:17:09
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site muscle pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Jan 2021 18:50:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:50:05
Data point term sent to Coder	System	22 Jan 2021 18:49:47
User entered 'muscle aches at injection site'	Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	Junlin Long (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '10:00'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
User entered '15 Jan 2021 10:00'	System	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '21:00'	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
User entered '15 Jan 2021 21:00'	System	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	Junlin Long (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	Junlin Long (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	Junlin Long (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Related (RELATED)'	Junlin Long (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Related (RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:47:06
Signature has been broken.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:38:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:38:05
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'None (NONE)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
Signature has been broken.	Junlin Long (b) (4)	23 Feb 2021 19:02:05
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'I'	(b) (4) Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
Signature has been broken.	Junlin Long (b) (4)	24 Feb 2021 19:04:42
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	(b) (4) Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	Junlin Long (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	22 Jan 2021 18:49:30
	(b) (4)	

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
User entered '0'	System	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52
User entered '0'	System	22 Jan 2021 18:49:30

US3622142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:52

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 13:49:39
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:12:35
User entered		
'USA-US085-2021-mRNA-1273-P301000009'	System	03 Feb 2021 17:12:30
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 17:12:30

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
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) (b) (4)	02 Feb 2021 16:49:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 16:49:29
Data point term sent to Coder	System	02 Feb 2021 16:48:33
User entered 'covid-19'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '26 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:00:31
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:35:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: The event, COVID-19, was considered resolved with sequel on 15 Feb 2021. Last reported COVID-19 symptoms in the log was 12 Feb 2021. Please provide updated COVID-19 symptom log. If not collected, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 16:37:28
Query 'PV Query: The event, COVID-19, was considered resolved with sequel on 15 Feb 2021. Last reported COVID-19 symptoms in the log was 12 Feb 2021. Please provide updated COVID-19 symptom log. If not collected, please state so.' answered with 'participant was tested negative of covid-19 on 15FEB2021. the results are negative. daily illness call showed participant stopped having symptoms before 12FEB2021, which was the last day on symptom log.' (Site from Safety).	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16
User opened query 'PV Query: The event, COVID-19, was considered resolved with sequel on 15 Feb 2021. Last reported COVID-19 symptoms in the log was 12 Feb 2021. Please provide updated COVID-19 symptom log. If not collected, please state so.' (Site from Safety). DataPoint Verified.	Junlin Long (b) (4) (b) (4)	11 Mar 2021 13:13:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:37:13
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 'end date provided' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '15 Feb 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 21:17:37
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).	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:37:38
User entered '15 Feb 2021' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:35:39
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 12:36:32

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '31 Jan 2021'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:54:58
Query 'PV Query: Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' answered with 'ae term - worsening covid-19 - has been updated.' (Site from Safety).	Junlin Long (b) (4)	22 Mar 2021 12:38:50
User opened query 'PV Query: Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' (Site from Safety).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	18 Mar 2021 13:53:28
DataPoint Verified.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16
	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	02 Feb 2021 16:48:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:13:21
User entered 'None (NONE)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:46:52
User closed query 'Per CDM: During OL -D1 visit subject has taken IP on 15JAN2021. So the AE started before the last dose. So please reconsider to update 'NONE' if study dose was not changed due to this adverse event as per CCG V4.0 page 47.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 09:46:27
Query 'Per CDM: During OL -D1 visit subject has taken IP on 15JAN2021. So the AE started before the last dose. So please reconsider to update 'NONE' if study dose was not changed due to this adverse event as per CCG V4.0 page 47.' answered with 'based on Moderna cove study MRNA-1273-P301: Weekly question and answer session, this answer should be not applicable.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:35:19
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' answered with 'based on Moderna cove study MRNA-1273-P301: Weekly question and answer session, this answer should be not applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 14:34:44
User opened query 'Per CDM: During OL -D1 visit subject has taken IP on 15JAN2021. So the AE started before the last dose. So please reconsider to update 'NONE' if study dose was not changed due to this adverse event as per CCG V4.0 page 47.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:25:55
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 12:38:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Feb 2021 16:58:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Feb 2021 16:48:22
User entered '0'	Junlin Long (b) (4)	02 Feb 2021 16:48:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '1' reason for change: New Information	Junlin Long (b) (4)	04 Feb 2021 16:58:42
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '1' reason for change: New Information	Junlin Long (b) (4)	04 Feb 2021 16:58:42
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:17:41
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'final outcome provided' (Site from Safety).	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:37:56
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:35:39
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)	12 Feb 2021 12:37:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'SHORTNESS OF BREATH on exertion' reason for change: New Information	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:55:32
User entered 'shortness of breath' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:35:39
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 16:48:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, this is not consistent with the recorded UNIT in the ConMed eCRF (CM eCRF recording = 1250 IU). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:24:23
Query 'Per DM CLR - RQ: Site's response noted. However, this is not consistent with the recorded UNIT in the ConMed eCRF (CM eCRF recording = 1250 IU). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'conmed #13 updated' (Site from DM).	Junlin Long (b) (4)	24 Mar 2021 12:59:05
User opened query 'Per DM CLR - RQ: Site's response noted. However, this is not consistent with the recorded UNIT in the ConMed eCRF (CM eCRF recording = 1250 IU). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:21:30
User closed query 'PV Query: Please assess the additional admitting diagnoses meet criteria for separate AE/SAE reporting: acute respiratory disease due to COVID-19 virus, hyponatremia, and hyperglycemia.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:37:21
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16
Query 'PV Query: Please assess the additional admitting diagnoses meet criteria for separate AE/SAE reporting: acute respiratory disease due to COVID-19 virus, hyponatremia, and hyperglycemia.' answered with 'acute respiratory disease was secondary to covid-19, so it has not been reported separately. hyponatremia and worsening hyperglycemia have been reported already.' (Site from Safety).	Junlin Long (b) (4)	11 Mar 2021 13:16:00
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:11:08
User closed query 'PV Query: Please assess if itching and rash (due to remdesivir infusion) meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:11:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' answered with 'correct as entered' (Site from Safety).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:07:37
Query 'PV Query: Please assess if itching and rash (due to remdesivir infusion) meets criteria for separate AE/SAE reporting.' answered with 'itching and rash reported' (Site from Safety).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:06:24
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:41:16
User opened query 'PV Query: Please assess if itching and rash (due to remdesivir infusion) meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:40:07
User opened query 'PV Query: Please assess the additional admitting diagnoses meet criteria for separate AE/SAE reporting: acute respiratory disease due to COVID-19 virus, hyponatremia, and hyperglycemia.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:39:48
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'Per DM CLR: Narrative = VITAMIN D 1,250MCG. However, the unit does not correspond to the recordings in the CM eCRF. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:37:59
User closed query 'Per DM CLR: Narrative = SODIUM 124, GLUCOSE 404, D-DIMER 0.55, PT 100, INR 13, CRP 100. However, this is not recorded in the ConProc eCRF (i.e., Blood Work-up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:03:27
Query 'Per DM CLR: Narrative = VITAMIN D 1,250MCG. However, the unit does not correspond to the recordings in the CM eCRF. Please review and update eCRF as appropriate.' answered with 'please refer to conmed line 13.' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:10:17

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Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SODIUM 124, GLUCOSE 404, D-DIMER 0.55, PT 100, INR 13, CRP 100. However, this is not recorded in the ConProc eCRF (i.e., Blood Work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'conproc page has been updated.' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:07:15
User opened query 'Per DM CLR: Narrative = VITAMIN D 1,250MCG. However, the unit does not correspond to the recordings in the CM eCRF. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:22:49
User opened query 'Per DM CLR: Narrative = SODIUM 124, GLUCOSE 404, D-DIMER 0.55, PT 100, INR 13, CRP 100. However, this is not recorded in the ConProc eCRF (i.e., Blood Work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:22:41
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:13:43
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 26 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:13:30
User closed query 'PV Query: Please assess if itching and rash (due to remdesivir infusion) meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:13:07
User closed query 'PV Query: Please assess the additional admitting diagnoses meet criteria for separate AE/SAE reporting: acute respiratory disease due to COVID-19 virus, hyponatremia, and hyperglycemia' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:13:00

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'US3622142's hospital discharge summary (29JAN2021 - 31JAN2021) has been sent to the provided email.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:13:32
Query 'PV Query: COVID-19 symptoms have been reported starting on 26 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'start date of covid-19 has been updated per query.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:01:09
Query 'PV Query: Please assess if itching and rash (due to remdesivir infusion) meets criteria for separate AE/SAE reporting.' answered with 'itching and rash have been reported as AEs.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:56:34
Query 'PV Query: Please assess the additional admitting diagnoses meet criteria for separate AE/SAE reporting: acute respiratory disease due to COVID-19 virus, hyponatremia, and hyperglycemia' answered with 'acute respiratory disease was due to covid-19. hyponatremia and hyperglycemia have been reported as AEs.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:48:04
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4)	12 Feb 2021 12:39:11
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 26 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	12 Feb 2021 12:38:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please assess if itching and rash (due to remdesivir infusion) meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 12:38:01
User opened query 'PV Query: Please assess the additional admitting diagnoses meet criteria for separate AE/SAE reporting: acute respiratory disease due to COVID-19 virus, hyponatremia, and hyperglycemia' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 12:37:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT CONTACTED SITE STATING THAT THEY WENT TO EMERGENCY ROOM ON 01/29/2021 BECAUSE THEY WERE EXPERIENCING COVID-19 SYMPTOMS. PARTICIPANT THEN WAS TESTED COVID-19 POSITIVE. THEY WERE ADMITTED TO HOSPITAL FROM 01/29/2021 TO 1/31/2021. update: Hospital admission for COVID 19 January 29, 2021 through January 31, 2021 The participant went to the ER on January 29, 2021 with chief complaint of cough, shortness of breath, and fatigue. Per ER documentation she was 93% on room air and decreased to 90% after 45 seconds of stress testing. She was tested for COVID 19 and was found to be positive. Participant was admitted and admitting diagnoses included hypoxia, acute respiratory disease due to COVID-19 virus, and COVID-19. Additional diagnoses included hyponatremia and hyperglycemia. Relevant lab results on 01/29/2021 included SARS-CoV-2RNA positive, sodium 124, glucose 404, D-dimer 0.55, PT 100, INR 13, CRP 100. Chest x-ray on 01/29/2021 with small patchy opacities at the periphery of bilateral mid to lower lungs. The participant received convalescent plasma on January 29, 2021. She reports that she received 2 doses of Remdesivir however, the hospital records show that the infusion was stopped due to itching and rash. Additional medications given for COVID 19 included doxycycline 100mg BID, dexamethasone 6mg daily, colchicine 0.6mg, Vitamin C 1,000 mg daily, Vitamin D 1,250mcg, and zinc sulfate 220mg daily. Lovenox 40mg subcutaneous was given for the prevention of blood clots and Humalog 2units and Lantus 6 units were given for hyperglycemia. The participant has a documented history of asthma, DM, and hypertension. She was discharged home on January 31, 2021 in stable condition.' reason for change: New Information	Junlin Long (b) (4) (b) (4)	05 Feb 2021 15:53:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'participant contacted site stating that they went to emergency room on 01/29/2021 because they were experiencing covid-19 symptoms. participant then was tested covid-19 positive. they were admitted to hospital from 01/29/2021 to 1/31/2021.'	Junlin Long (b) (4)	02 Feb 2021 16:48:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 16:48:22

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:33:41
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:33:38
User entered 'USA-US085-2021-mRNA-1273-P301000009' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 16:33:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:30:42
User entered 'USA-US085-2021-mRNA-1273-P301000012'	System	09 Feb 2021 17:30:27
User entered 'New'	(b) (4), (b) (6)	09 Feb 2021 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM: please clarify why this has not been ticked as part of confirmed COVID-19 diagnosis. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 20:21:13
User opened query 'Per MM: please clarify why this has not been ticked as part of confirmed COVID-19 diagnosis. ' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 20:13:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:20:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:20:50
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Per DM CLR: Please note this AE overlaps with AE #2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:54:57
User closed query 'PV Query: Regarding the SAE of worsening COVID-19, please consider whether the event might be updated to the discharge diagnosis of acute hypoxemic respiratory failure secondary to COVID-19 considering that the event dates coincide with the hospitalization for this diagnosis.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:53:19
User closed query 'Per DM CLR: Please confirm the AE term "WORSENING COVID-19", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 05:15:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 14:38:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 14:38:46
Query 'Per DM CLR: Please confirm the AE term "WORSENING COVID-19", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'ae term updated' (Site from DM).	Junlin Long (b) (4)	22 Mar 2021 12:35:03
Query 'Per DM CLR: Please note this AE overlaps with AE #2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4)	22 Mar 2021 12:34:26
Query 'PV Query: Regarding the SAE of worsening COVID-19, please consider whether the event might be updated to the discharge diagnosis of acute hypoxemic respiratory failure secondary to COVID-19 considering that the event dates coincide with the hospitalization for this diagnosis.' answered with 'updated' (Site from Safety).	Junlin Long (b) (4)	22 Mar 2021 12:33:24
Data point term sent to Coder	System	22 Mar 2021 12:33:23
DataPoint Un-verified.	Junlin Long (b) (4)	22 Mar 2021 12:33:14
Coding entries removed.	Junlin Long (b) (4)	22 Mar 2021 12:33:14
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:33:14
User entered 'acute hypoxemic respiratory failure secondary to COVID-19' reason for change: Per Query Resolution	Junlin Long (b) (4)	22 Mar 2021 12:33:14

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please confirm the AE term "WORSENING COVID-19", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:24:03
User opened query 'Per DM CLR: Please note this AE overlaps with AE #2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:23:57
User opened query 'PV Query: Regarding the SAE of worsening COVID-19, please consider whether the event might be updated to the discharge diagnosis of acute hypoxemic respiratory failure secondary to COVID-19 considering that the event dates coincide with the hospitalization for this diagnosis.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 13:52:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	06 Mar 2021 15:32:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 15:32:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
Data point term sent to Coder	System	25 Feb 2021 18:32:40
Coding entries removed.	Junlin Long (b) (4)	25 Feb 2021 18:31:40
User entered 'worsening covid-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	25 Feb 2021 18:31:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 12:55:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 12:55:32

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	08 Feb 2021 12:55:17
User entered 'hypoxia'	Junlin Long (b) (4)	08 Feb 2021 12:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please clarify why this has not been ticked as part of confirmed COVID-19 diagnosis. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 10:48:08
Query 'Per MM: please clarify why this has not been ticked as part of confirmed COVID-19 diagnosis. ' answered with 'This AE was secondary to COVID-19, but was not symptomatic COVID-19 per se.' (Site from DM).	Junlin Long (b) (4)	26 Apr 2021 12:41:34
User opened query 'Per MM: please clarify why this has not been ticked as part of confirmed COVID-19 diagnosis. ' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 20:21:11
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4)	08 Feb 2021 12:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '6 Feb 2021'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 10:48:11
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 'End date provided. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:30:15
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:55:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:31:14
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '9 Feb 2021' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:31:14
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:07:23
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).	(b) (4), (b) (6)	16 Feb 2021 17:17:52
User entered empty.	System	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 21:03:35
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 21:03:26
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Feb 2021 19:26:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	23 Feb 2021 19:26:25
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	08 Feb 2021 12:54:57
User entered 'I'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '6 Feb 2021'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:15:49
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'discharge date provided' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:26:38
User entered '9 Feb 2021' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:26:25
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:22:23
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	23 Feb 2021 19:26:25
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		23 Feb 2021 19:26:25
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:26:25
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Feb 2021 12:54:57
User entered 'Unknown (UNK)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:53:42
Query 'PV Query: Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' answered with 'ae term updated' (Site from Safety).	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:35:22
User opened query 'PV Query: Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 13:51:50
Query 'Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 13:51:38
User opened query 'Please provide the Investigator's rationale for the SAEs of COVID-19 and worsening of COVID-19, considering that the dates for worsening of COVID-19 overlap with the dates of COVID-19.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 13:51:28
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 21:02:54
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 21:02:49
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:14:47
Query 'Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' answered with 'updated' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:45:31
User entered 'None (NONE)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:45:20
User opened query 'Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:20:21
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Feb 2021 19:31:14
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Feb 2021 12:54:57
User entered '0'	Junlin Long (b) (4)	08 Feb 2021 12:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '1' reason for change: New Information	Junlin Long (b) (4)	23 Feb 2021 19:31:14
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 05:16:03
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'updated' (Site from DM).	Junlin Long (b) (4)	22 Mar 2021 12:37:47
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	22 Mar 2021 12:37:41
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:37:41
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4)	22 Mar 2021 12:37:41
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:24:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '1' reason for change: New Information	Junlin Long (b) (4)	23 Feb 2021 19:31:14
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	08 Feb 2021 12:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:33:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:31:14
Query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:29:32
User opened query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:19:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'SHORTNESS OF BREATH ON EXERTION' reason for change: New Information	Junlin Long (b) (4)	25 Feb 2021 18:56:16
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)	24 Feb 2021 14:16:07
Query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'outcome provided' (Site from Safety).	Junlin Long (b) (4)	23 Feb 2021 19:34:03
	(b) (4)	
User entered 'hypoxia' reason for change: Per Query Resolution	Junlin Long (b) (4)	23 Feb 2021 19:33:33
	(b) (4)	
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)	16 Feb 2021 17:29:53
User entered empty.	Junlin Long (b) (4)	08 Feb 2021 12:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = 2L NASAL CANULA. However, this is not recorded in the ConProc/ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 14:30:56
User closed query 'Per DM CLR: Narrative = SIGNIFICANT LABS FROM FEBRUARY 06, 2021 INCLUDED, SODIUM 130 (L), POTASSIUM 3.2 (L), CRP 53.8 (H), LACTIC ACID 2.2 (H), D-DIMER 1.37 (H). 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 14:30:55
Query 'Per DM CLR: Narrative = 2L NASAL CANULA. However, this is not recorded in the ConProc/ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4)	24 Mar 2021 12:53:25
Query 'Per DM CLR: Narrative = SIGNIFICANT LABS FROM FEBRUARY 06, 2021 INCLUDED, SODIUM 130 (L), POTASSIUM 3.2 (L), CRP 53.8 (H), LACTIC ACID 2.2 (H), D-DIMER 1.37 (H). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4)	24 Mar 2021 12:51:05
User opened query 'Per DM CLR: Narrative = SIGNIFICANT LABS FROM FEBRUARY 06, 2021 INCLUDED, SODIUM 130 (L), POTASSIUM 3.2 (L), CRP 53.8 (H), LACTIC ACID 2.2 (H), D-DIMER 1.37 (H). 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)	19 Mar 2021 00:23:30
User opened query 'Per DM CLR: Narrative = 2L NASAL CANULA. However, this is not recorded in the ConProc/ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:23:23
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:11:57
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' answered with 'this SAE started between participant's 1st dose and 2nd dose, so the action taken should be "None" per protocol.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:10:20
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 15 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:41:49
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:18:16
User closed query 'PV Query: Please provide treatment given for the event, hypoxia including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:18:12
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'medical records have been sent to the provided email (Safety_Moderna@iqvia.com).' (Site from Safety).	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:58:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event, hypoxia including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'conmed page has been updated.' (Site from Safety). User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:57:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Feb 2021 16:37:05
	System	25 Feb 2021 16:37:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Medical records from hospital admission have been reviewed. The participant went to the ER for worsening SOB on February 06, 2021. Records state that she presented with oxygen saturation at 89% on room air which improved to 98% with 2L nasal canula. Findings included worsening COVID related pneumonia and hypoxia and she was admitted. Significant labs from February 06, 2021 included SARS-CoV-2RNA positive, sodium 130 (L), potassium 3.2 (L), CRP 53.8 (H), lactic acid 2.2 (H), D-Dimer 1.37 (H). Chest x-ray on February 06, 2021 with bilateral peripheral airspace opacities concerning for multifocal pneumonia, slightly more prominent compared to prior and consistent with patient's positive COVID-19 status. CTA of the chest on February 09, 2021 was negative for PE but revealed extensive bilateral multifocal consolidative and ground glass opacities. She was found to have bilateral lower extremity edema for which she was given IV Lasix. EKG on 02/06/2021 and echocardiogram on 02/09/2021 were both normal. Medications given during admission include albuterol inhaler, aspirin, colchicine, decadron, doxycycline, lovenox, lasix, robitussin, humalog, potassium chloride and vancomycin. She remained with oxygen saturation at 95% or greater while admitted and was discharged home in stable condition on 02/09/2021.' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	25 Feb 2021 16:37:05
User closed query 'PV Query: Please confirm hypoxia was a separate hospitalization from COVID-19.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 14:15:08
Query 'PV Query: Please confirm hypoxia was a separate hospitalization from COVID-19.' answered with 'participant had two hospitalizations; the first one was due to sae covid-19. the second one was due to sae hypoxia.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:44:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:22:53
User opened query 'PV Query: Please confirm hypoxia was a separate hospitalization from COVID-19.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:22:02
User opened query 'PV Query: Please provide treatment given for the event, hypoxia including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:21:12
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	08 Feb 2021 12:54:57
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Feb 2021 12:54:57

US3622142

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Feb 2021 12:54:57

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Mar 2021 15:28:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 15:28:03
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
Data point term sent to Coder	System	02 Mar 2021 18:21:50
Coding entries removed.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:21:01
User entered 'worsening HYPERGLYCEMIA' reason for change: New Information	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:21:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 18:42:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 18:42:12
Data point term sent to Coder	System	23 Feb 2021 18:41:03
User entered 'hyperglycemia'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User entered empty.	System	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:23:50
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:30:39
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:30:39
User entered '9 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	17 Mar 2021 16:30:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '6 Feb 2021' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:23:50
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User entered empty.	System	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:23:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User entered '0'	System	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03
User entered 'I'	System	23 Feb 2021 18:40:14

US3622142

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 18:46:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 18:46:03
Data point term sent to Coder	System	23 Feb 2021 18:45:14
User entered 'hyponatremia'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User entered empty.	System	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:00:11
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:00:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:00:11
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:00:21
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).	System	17 Mar 2021 16:00:21
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	17 Mar 2021 16:00:11
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:00:11
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:00:11
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:00:11
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User entered empty.	System	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	Junlin Long (b) (4)	22 Mar 2021 12:41:22
Signature has been broken.	(b) (4) Junlin Long (b) (4)	22 Mar 2021 12:41:22
User entered '1' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	22 Mar 2021 12:41:22
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 05:16:23
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:41:29
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:41:22
Signature has been broken.	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:41:22
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:41:22
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:25:05
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '1'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:40
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:00:21
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:00:21
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:00:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

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Folder: Adverse Events

Form: Adverse Events (6)

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[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 12:40:45
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	17 Mar 2021 16:01:40
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	17 Mar 2021 16:00:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User entered '0'	System	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User entered 'I'	System	23 Feb 2021 18:44:51

US3622142

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of ITCHING. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:04:16
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Generalized itching - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 14:06:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 14:06:33
Data point term sent to Coder	System	19 Mar 2021 14:05:37
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of ITCHING. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:04:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 14:04:44
Coding entries removed.	(b) (4), (b) (6)	19 Mar 2021 14:04:44
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:04:44
User entered 'generalized ITCHING' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:04:44
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of ITCHING. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:25:14
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Itching - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 19:11:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 19:11:09
Data point term sent to Coder	System	23 Feb 2021 18:55:24
User entered 'itching'	Junlin Long (b) (4)	23 Feb 2021 18:54:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User entered empty.	System	23 Feb 2021 18:54:51

US3622142

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '31 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

US3622142

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User entered empty.	System	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

US3622142

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:11:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Form: Adverse Events (7)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User entered '0'	System	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48
User entered 'I'	System	23 Feb 2021 18:54:51

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:26:48

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Drug rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:52:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:52:29
User closed query 'Per DM CLR RQ: Response noted. However, please review and record the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial if known. Please reconcile and update AE and the corresponding conmed as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 04:39:17
Query 'Per DM CLR RQ: Response noted. However, please review and record the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial if known. Please reconcile and update AE and the corresponding conmed as appropriate, else clarify.' answered with 'Medical records do not specify the type of rash.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:15:31
User opened query 'Per DM CLR RQ: Response noted. However, please review and record the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial if known. Please reconcile and update AE and the corresponding conmed as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:06:23
User closed query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 10:51:27

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EAB) (1725)

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[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	17 Mar 2021 15:45:58
User closed query 'For coding purpose: for AE term RASH, please clarify the location and specific type of rash, e.g. macular, papular, acneiform, drug related etc. Please update the term accordingly.' (Site from System).	System	17 Mar 2021 15:45:44
Query 'For coding purpose: for AE term RASH, please clarify the location and specific type of rash, e.g. macular, papular, acneiform, drug related etc. Please update the term accordingly.' answered with 'updated.' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 15:45:44
User entered 'RASH (RELATED TO REMDESIVIR)' reason for change: Data Entry Error DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 15:45:37
	(b) (4), (b) (6)	17 Mar 2021 15:45:28
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 15:45:28
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 15:45:28
User entered 'RASH(RELATED TO REMDESIVIR)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 15:45:28
Query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'ACCORDING TO MEDICAL RECORDS THE TYPE AND LOCATION OF RASH WERE SPECIFIED ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:42:32
User opened query 'For coding purpose: for AE term RASH, please clarify the location and specific type of rash, e.g. macular, papular, acneiform, drug related etc. Please update the term accordingly.' (Site from System).	Coder Import (b) (4)	17 Mar 2021 11:13:52

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	16 Mar 2021 10:26:11
DataPoint Verified.	Susanne Doblecki-Lewis (b) (4) (b) (4), (b) (6)	12 Mar 2021 13:12:16 05 Mar 2021 13:49:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 18:56:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 18:56:09
Data point term sent to Coder	System	23 Feb 2021 18:55:24
User entered 'rash'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User entered empty.	System	23 Feb 2021 18:55:23

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '31 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User entered empty.	System	23 Feb 2021 18:55:23

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[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 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User entered '0'	System	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34
User entered 'I'	System	23 Feb 2021 18:55:23

US3622142

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:34

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
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) (b) (4)	23 Feb 2021 19:19:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 19:19:08
Data point term sent to Coder	System	23 Feb 2021 19:18:22
User entered 'pneumonia'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '29 Jan 2021'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User entered empty.	System	23 Feb 2021 19:17:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:03:10
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:03:10
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:03:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:03:10
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:02:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:03:10
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).	System	17 Mar 2021 16:03:10
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	17 Mar 2021 16:02:59
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:02:59
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:02:59
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:02:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User entered empty.	System	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:03:10
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:03:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:03:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[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 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User entered '0'	System	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23
User entered 'I'	System	23 Feb 2021 19:17:35

US3622142

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:23

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Acid-base disorders, HLT: Metabolic acidoses (excl diabetic acidoses), PT: Lactic acidosis, LLT: Lactic acidosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:03:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:03:02
Data point term sent to Coder	System	24 Feb 2021 19:02:42
User entered 'lactic acidosis'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '6 Feb 2021'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User entered empty.	System	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:04:03
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:04:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:04:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:04:03
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:04:03
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:04:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User entered empty.	System	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:04:03
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:04:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:04:03
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[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 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User entered '0'	System	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15
User entered 'I'	System	24 Feb 2021 19:01:57

US3622142

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:15

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:04:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:04:12
Data point term sent to Coder	System	24 Feb 2021 19:03:44
User entered 'hypokalemia'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '6 Feb 2021'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User entered empty.	System	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '8 Feb 2021'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User entered empty.	System	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User entered '0'	System	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06
User entered 'I'	System	24 Feb 2021 19:02:48

US3622142

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:27:06

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:04:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:04:59
Data point term sent to Coder	System	24 Feb 2021 19:04:46
User entered 'bilateral lower extremity edema'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '8 Feb 2021'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User entered empty.	System	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:22:06
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:22:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:22:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:22:16
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).	System	17 Mar 2021 16:22:16
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	17 Mar 2021 16:22:06
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:22:06
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:22:06
User entered '01 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:22:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User entered empty.	System	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:22:16
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:22:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:22:16
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[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 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User entered '0'	System	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02
User entered 'I'	System	24 Feb 2021 19:03:46

US3622142

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:02

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:01:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:01:02
Data point term sent to Coder	System	25 Feb 2021 19:00:36
User entered 'shortness of breath on exertion'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '26 Jan 2021'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User entered empty.	System	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:20:56
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:20:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:20:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:20:56
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:20:56
User entered '02 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:20:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User entered empty.	System	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

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Folder: Adverse Events

Form: Adverse Events (14)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'l'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered '0'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 16:20:56
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:20:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:20:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[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 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:49:39
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User entered '0'	System	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52
User entered 'I'	System	25 Feb 2021 19:00:06

US3622142

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:52

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Folder: Adverse Events

Form: Adverse Events (15)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:26:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:26:05
Data point term sent to Coder	System	17 Mar 2021 16:25:06
User entered 'hypothyroidism'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:25:22
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	17 Mar 2021 16:25:22
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:24:57
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).	System	17 Mar 2021 16:24:57
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	17 Mar 2021 16:24:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:24:57
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	17 Mar 2021 16:24:45
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 16:24:35

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 16:24:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 16:24:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:24:45
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 16:24:35
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:21
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 16:24:35

US3622142

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:11:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 16:24:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:11:43

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:17
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:23
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 22:19:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 22:19:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 22:19:31
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:19:26
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 22:19:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 22:22:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:22:46
Data point term sent to Coder	System	10 Sep 2020 22:21:36
User entered 'metformin'	(b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'diabetes'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '850'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 22:20:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 22:23:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:23:47
Data point term sent to Coder	System	10 Sep 2020 22:22:38
User entered 'losartan'	(b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '100/12.5'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 22:21:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:24:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:24:50
Data point term sent to Coder	System	10 Sep 2020 22:23:41
User entered 'vitamin e'	(b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Prophylaxis'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '400'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:22:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:29:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:29:35
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	13 Sep 2020 16:31:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN-C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:26:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:26:51
Data point term sent to Coder	System	10 Sep 2020 22:25:52
User entered 'vitamin c'	(b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Prophylaxis'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '500'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:26:22
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:04:29
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'corrected' (Site from DM).	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:25:30
Signature has been broken.	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:25:07
User entered 'No (N)' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	29 Oct 2020 15:25:07
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:49:54
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:25:42

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	(b) (4)	
	Coder Import (b) (4)	10 Sep 2020 22:32:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 22:32:46
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 22:31:59
User entered 'flu vaccine'	(b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Prophylaxis'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '0.5'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'yearly'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
Signature has been broken.	(b) (4), (b) (6)	15 Sep 2020 15:34:58
User entered '15 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 15:34:58
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'un Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:58:49
Signature has been broken.	(b) (4), (b) (6)	15 Sep 2020 15:34:58
User entered '15 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 15:34:58
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'un Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:50:41
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:31:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
User entered empty.	System	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
User entered empty.	System	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:26
User entered empty.	System	10 Sep 2020 22:31:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 18:19:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:19:43
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:18:47 02 Mar 2021 18:17:49
Signature has been broken.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:17:49
User entered 'ADVAir' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:17:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	28 Jan 2021 15:08:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:58:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:58:18
Data point term sent to Coder	System	22 Jan 2021 18:56:55
User entered 'advair 500/50'	Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:56:47

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EAB) (1725)

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US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'asthma'	Junlin Long (b) (4)	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
Signature has been broken.	Junlin Long	02 Mar 2021 18:17:49
User entered '500/50' reason for change: Per Query Resolution	Junlin Long	02 Mar 2021 18:17:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'I'	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
Signature has been broken.	Junlin Long	02 Mar 2021 18:17:49
User entered 'ug (ug)' reason for change: Per Query Resolution	Junlin Long	02 Mar 2021 18:17:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Other (OTHER)'	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (e.g. puff). Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 09:20:07
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (e.g. puff). Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:18:02
Signature has been broken.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:17:49
User entered empty; reason for change Per Query Resolution	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:17:49
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (e.g. puff). Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:43:22
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'inhale'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'twice daily (BID)'	Junlin Long (b) (4)	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'un Feb 2017'	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered '0'	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:08:09
User entered 'No (N)'	Junlin Long	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Jan 2021 18:56:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
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.	Coder Import (b) (4) (b) (4)	23 Feb 2021 19:19:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 19:19:07
Data point term sent to Coder	System	23 Feb 2021 19:03:39
Coding entries removed.	Junlin Long (b) (4) (b) (4)	23 Feb 2021 19:02:57
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:03:57
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.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:42:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:42:33
Data point term sent to Coder	System	04 Feb 2021 17:20:26
Coding entries removed.	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:19:53
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.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:05:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:05:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	04 Feb 2021 17:05:07
User entered 'azithromycin'	Junlin Long (b) (4)	04 Feb 2021 17:04:33
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	23 Feb 2021 19:02:57
User entered 'COVID-19' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	23 Feb 2021 19:02:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered 'COVID-19 symptoms' reason for change: New Information	Junlin Long (b) (4)	04 Feb 2021 17:19:53
	(b) (4)	
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:04:33
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '500'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:04:33
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:04:33
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '26 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '28 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
User entered '1'	System	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
User entered '1'	System	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:31
User entered '804 (804)'	System	04 Feb 2021 17:04:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 20:58:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:58:29
Data point term sent to Coder	System	04 Feb 2021 17:26:35
User entered 'doxycycline'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '100'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:26:33
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'twice daily (BID)'	Junlin Long (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:26:33
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:26:33
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:20:15
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:06:45
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:06:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:06:39
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:21:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:06:39
User entered '06 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:06:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
User entered '2'	System	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
User entered '1'	System	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:37
User entered '804 (804)'	System	04 Feb 2021 17:26:33

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 17:29:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:29:49
Data point term sent to Coder	System	04 Feb 2021 17:28:38
User entered 'dexamethasone'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '6'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:28:27
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:28:27
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:20:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:08:15
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:08:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:08:10
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:21:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:08:10
User entered '06 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:08:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
User entered '1'	System	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
User entered '1'	System	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:41
User entered '804 (804)'	System	04 Feb 2021 17:28:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 20:54:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:54:29
Data point term sent to Coder	System	04 Feb 2021 17:31:42
User entered 'colchicine'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0.6'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:30:54
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:30:54
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:20:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:08:40
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:08:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:08:35
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:22:00
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:08:35
User entered '06 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:08:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
User entered '1'	System	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
User entered '1'	System	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:46
User entered '804 (804)'	System	04 Feb 2021 17:30:54

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 17:33:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:33:51
Data point term sent to Coder	System	04 Feb 2021 17:32:44
User entered 'remdesivir'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '200'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:32:26
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
	Junlin Long	04 Feb 2021 17:53:44
User entered 'once daily (QD)'	(b) (4)	
	Junlin Long	04 Feb 2021 17:32:26
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:32:26
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 17:51:15
User entered 'No (N)' reason for change: Per Query Resolution	System	04 Feb 2021 17:51:15
User opened query 'Data is required. Please complete.' (Site from System).	Junlin Long (b) (4)	04 Feb 2021 17:51:15
User entered empty.	(b) (4)	
	System	04 Feb 2021 17:32:26
	Junlin Long (b) (4)	04 Feb 2021 17:32:26
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
User entered empty.	System	04 Feb 2021 17:53:44
User entered '1'	System	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
User entered empty.	System	04 Feb 2021 17:53:44
User entered '1'	System	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:51
User entered empty.	System	04 Feb 2021 17:53:44
User entered '804 (804)'	System	04 Feb 2021 17:32:26

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 17:35:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:35:47
Data point term sent to Coder	System	04 Feb 2021 17:34:54
User entered 'vitamin c'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '1,000'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:34:50
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:34:50
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:34:50
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:20:52
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:09:28
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:09:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:09:23
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:22:11
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:09:23
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:09:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User entered '1'	System	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User entered '1'	System	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User entered '804 (804)'	System	04 Feb 2021 17:34:50

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 17:38:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:38:47
Data point term sent to Coder	System	04 Feb 2021 17:37:55
User entered 'vitamin d'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User closed query 'Per CDM: Per CCGs, large numbers should be entered as they are with no additional spaces, commas or periods. When separating decimals, a period "." should be used, not a comma. Please review the dose and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:34:36
Query 'Per CDM: Per CCGs, large numbers should be entered as they are with no additional spaces, commas or periods. When separating decimals, a period "." should be used, not a comma. Please review the dose and update this field as appropriate. ' answered with 'Updated.' (Site from DM).	Junlin Long (b) (4) (b) (4)	07 Apr 2021 15:59:37
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 15:59:29
Signature has been broken.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 15:59:29
User entered '1250' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	07 Apr 2021 15:59:29
User opened query 'Per CDM: Per CCGs, large numbers should be entered as they are with no additional spaces, commas or periods. When separating decimals, a period "." should be used, not a comma. Please review the dose and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:45:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:03:57
User entered '1,250'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:46:30
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'Correct as entered; mcg and ug are the same.' (Site from DM).	Junlin Long (b) (4) (b) (4)	06 Apr 2021 15:55:01
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:22:52
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	26 Mar 2021 20:09:56
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	24 Mar 2021 12:58:43
Signature has been broken.	Junlin Long (b) (4) (b) (4)	24 Mar 2021 12:58:43
User entered 'ug (ug)' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	24 Mar 2021 12:58:43
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:03:57
User entered 'IU (IU)'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:37:01
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:37:01
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:37:01
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:20:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:09:54
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:09:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:09:48
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:22:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:09:48
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:09:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
User entered '1'	System	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
User entered '1'	System	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:59
User entered '804 (804)'	System	04 Feb 2021 17:37:01

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 17:39:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:39:50
Data point term sent to Coder	System	04 Feb 2021 17:38:56
User entered 'zinc sulfate'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '220'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:38:11
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:38:11
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:38:11
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:21:06
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:10:11
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:10:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:10:06
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 00:22:28
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:10:06
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:10:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
User entered '1'	System	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
User entered '1'	System	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:08
User entered '804 (804)'	System	04 Feb 2021 17:38:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 22:52:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:52:28
Data point term sent to Coder	System	04 Feb 2021 17:39:58
User entered 'lovenox'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'prevention of clots'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '40'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:39:55
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
	Junlin Long	04 Feb 2021 17:52:11
User entered 'once daily (QD)'	(b) (4)	
	Junlin Long	04 Feb 2021 17:39:55
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:39:55
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Subcutaneous (SUBCUTANEOUS)'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '30 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '30 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
User entered empty.	System	04 Feb 2021 17:52:11
User entered '1'	System	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
User entered empty.	System	04 Feb 2021 17:52:11
User entered '1'	System	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:19
User entered empty.	System	04 Feb 2021 17:52:11
User entered '804 (804)'	System	04 Feb 2021 17:39:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 17:44:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:44:01
Data point term sent to Coder	System	04 Feb 2021 17:42:02
User entered 'remdesivir'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'covid-19'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '200'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:41:43
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once (ONCE)'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:41:43
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:41:43
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '30 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '30 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
User entered empty.	System	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
User entered empty.	System	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:32
User entered empty.	System	04 Feb 2021 17:41:43

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
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 SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:33:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:33:30
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:03:57
Data point term sent to Coder	System	04 Feb 2021 17:44:06
User entered 'protonix'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'prevention of reflux'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '40'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once (ONCE)'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:43:32
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:43:32
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
User entered empty.	System	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
User entered empty.	System	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:37
User entered empty.	System	04 Feb 2021 17:43:32

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:56:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:56:53
User closed query 'Per DM CLR: Con Med HUMALOG was added/changed on 31 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:00:48
Query 'Per DM CLR: Con Med HUMALOG was added/changed on 31 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'ae updated; please refer to ae log line 5.' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:23:00
Data point term sent to Coder	System	02 Mar 2021 18:22:51
Coding entries removed.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:22:26
User opened query 'Per DM CLR: Con Med HUMALOG was added/changed on 31 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:43:56

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 17:47:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:47:48
Data point term sent to Coder	System	04 Feb 2021 17:47:10
User entered 'humalog'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	02 Mar 2021 18:22:26
User entered 'worsening hyperglycemia' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	02 Mar 2021 18:22:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered 'diabetes'	Junlin Long (b) (4)	04 Feb 2021 17:47:04
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '2'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'unit'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once (ONCE)'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:47:04
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Subcutaneous (SUBCUTANEOUS)'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:47:04
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	04 Feb 2021 17:51:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 17:51:36
User entered 'No (N)' reason for change: Per Query Resolution	Junlin Long (b) (4)	04 Feb 2021 17:51:36
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 17:47:04
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:47:04
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
User entered empty.	System	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
User entered empty.	System	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:46
User entered empty.	System	04 Feb 2021 17:47:04

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:24:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:24:47
Data point term sent to Coder	System	02 Mar 2021 18:23:56
Coding entries removed.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:23:24
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:03:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:49:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:49:47
Data point term sent to Coder	System	04 Feb 2021 17:49:12
User entered 'lantus'	Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	02 Mar 2021 18:23:24
User entered 'worsening hyperglycemia' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	02 Mar 2021 18:23:24
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered 'diabetes'	Junlin Long (b) (4)	04 Feb 2021 17:48:27
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '6'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'unit'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once (ONCE)'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:48:27
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Subcutaneous (SUBCUTANEOUS)'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
User entered empty.	System	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
User entered empty.	System	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:51
User entered empty.	System	04 Feb 2021 17:48:27

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:58:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:58:03
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:34:58 12 Apr 2021 17:34:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:28:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:28:02
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	18 Mar 2021 12:13:24 18 Mar 2021 12:12:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:55:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:55:58
Data point term sent to Coder	System	02 Mar 2021 18:25:06
Coding entries removed.	Junlin Long (b) (4)	02 Mar 2021 18:24:57
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:03:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 20:28:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 20:28:41
Data point term sent to Coder	System	04 Feb 2021 17:50:13
User entered 'benadryl'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:41:49
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
User closed query 'Per DM CLR: Please specify the type of Rash (i.e., Urticarial or Non-Urticarial). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 10:26:02
Query 'Per DM CLR: Please specify the type of Rash (i.e., Urticarial or Non-Urticarial). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'Indication has been updated to match with AEs.' (Site from DM).	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:35:38
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:34:06
Signature has been broken.	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:34:06
User entered 'GENERALIZED ITCHY; RASH (related to remdesivir)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:34:06
User opened query 'Per DM CLR: Please specify the type of Rash (i.e., Urticarial or Non-Urticarial). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 13:57:07
Query 'Per DM CLR: Please specify the location and type of Rash (i.e., Urticarial or Non-Urticarial). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' canceled (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 13:56:56
User opened query 'Per DM CLR: Please specify the location and type of Rash (i.e., Urticarial or Non-Urticarial). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 13:56:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of ITCH, RASH. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:21:27
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Query 'Per DM CLR: Please specify the location of ITCH, RASH. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:12:50
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 12:12:44
User entered 'generalized ITCHY, RASH' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 12:12:44
User opened query 'Per DM CLR: Please specify the location of ITCH, RASH. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:41:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Per DM CLR: Please note there is no ongoing MH 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 MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 03:04:48
Query 'Per DM CLR: Please note there is no ongoing MH 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 MH or AE eCRF. ' answered with 'indication updated to match ae' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:25:19
Signature has been broken.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:24:57
User entered 'itchy, rash' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:24:57

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no ongoing MH 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 MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:43:45
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'allergic reaction to remdesivir'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '25'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:50:12
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'once (ONCE)'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:50:12
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Feb 2021 17:50:12
	(b) (4)	

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '31 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'No (N)'	Junlin Long (b) (4)	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
User entered empty.	System	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
User entered empty.	System	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:58
User entered empty.	System	04 Feb 2021 17:50:12

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
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.	Coder Import (b) (4) (b) (4)	22 Mar 2021 15:21:46
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 Mar 2021 15:21:46
Data point term sent to Coder	System	22 Mar 2021 12:44:31
Coding entries removed.	Junlin Long (b) (4)	22 Mar 2021 12:43:32
User closed query 'Per DM CLR: Con Med ALBUTEROL INHALER was added on 6 FEB 2021. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 08:32:09
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.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:17:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:17:48
Data point term sent to Coder	System	17 Mar 2021 15:54:09

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Con Med ALBUTEROL INHALER was added on 6 FEB 2021. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' answered with 'indication updated.' (Site from DM). Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 15:53:59
	(b) (4), (b) (6)	17 Mar 2021 15:53:38
User opened query 'Per DM CLR: Con Med ALBUTEROL INHALER was added on 6 FEB 2021. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	17 Mar 2021 10:10:01
	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
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)	24 Feb 2021 18:49:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Feb 2021 18:49:59
	(b) (4)	
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.	Coder Import (b) (4)	24 Feb 2021 18:35:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Feb 2021 18:35:02
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 18:34:41

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'albuterol inhaler'	(b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:56
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:43:32
User entered 'ACUTE HYPOXEMIC RESPIRATORY FAILURE SECONDARY TO COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	22 Mar 2021 12:43:32
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:38
User entered 'worsening of covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 15:53:38
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'asthma'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
User closed query 'Per DM CLR: Please review and remove the extraneous information (i.e. PUFFS (180MCG) from the DOSE field. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:00:51
Query 'Per DM CLR: Please review and remove the extraneous information (i.e. PUFFS (180MCG) from the DOSE field. Update eCRF as appropriate.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:47:45
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 15:47:38
User entered '180' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 15:47:38
User opened query 'Per DM CLR: Please review and remove the extraneous information (i.e. PUFFS (180MCG) from the DOSE field. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:10:11
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '2 puffs (180mcg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 15:47:38
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 15:47:38
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'puff (PUFF)'	(b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'every 4 hours as needed.'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered empty.	System	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered empty.	System	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered empty.	System	24 Feb 2021 18:33:56

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Feb 2021 18:38:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:38:00
Data point term sent to Coder	System	24 Feb 2021 18:37:50
Data point term sent to Coder	System	24 Feb 2021 18:34:41
User entered 'aspirin'	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:02
User entered 'prevention of blood clots' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:02
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:02
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:02
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:02
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
User entered '7 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:08
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:37:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:34:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
User entered '1'	System	24 Feb 2021 18:37:02
User entered empty.	System	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
User entered '1'	System	24 Feb 2021 18:37:02
User entered empty.	System	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:23
User entered '804 (804)'	System	24 Feb 2021 18:37:02
User entered empty.	System	24 Feb 2021 18:34:14

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:44:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:44:46
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4)	22 Mar 2021 12:44:31 22 Mar 2021 12:43:56
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 12:53:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 12:53:57
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4)	02 Mar 2021 18:12:38 02 Mar 2021 18:12:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Feb 2021 18:41:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:41:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Feb 2021 18:39:54
User entered 'colchicine'	(b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:56
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:43:56
User entered 'COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	22 Mar 2021 12:43:56
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'worsening COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	02 Mar 2021 18:12:17
User entered 'covid-19'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0.6'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
User closed query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 05:53:19
Query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:11:05
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 12:10:59
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 12:10:59
User opened query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:29:24
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
User entered empty.	System	18 Mar 2021 12:10:59
User entered '1'	System	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
User entered empty.	System	18 Mar 2021 12:10:59
User entered '1'	System	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:28
User entered empty.	System	18 Mar 2021 12:10:59
User entered '804 (804)'	System	24 Feb 2021 18:39:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Feb 2021 18:43:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:43:00
Data point term sent to Coder	System	24 Feb 2021 18:42:02
User entered 'decadron'	(b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
User entered '1'	System	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
User entered '1'	System	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:33
User entered '804 (804)'	System	24 Feb 2021 18:41:20

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 13:28:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:28:49
Data point term sent to Coder	System	24 Feb 2021 18:43:04
User entered 'doxycycline'	(b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '100'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
User entered empty.	System	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
User entered empty.	System	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:42
User entered empty.	System	24 Feb 2021 18:42:35

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Feb 2021 18:45:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:45:01
Data point term sent to Coder	System	24 Feb 2021 18:44:06
User entered 'lovenox'	(b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 05:53:42
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:13:24
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 12:09:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 12:09:52
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:32:22
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
User closed query 'Per DM CLR: Please review Con Med if also used for AE# 2 COVID-19 as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:29:11
Query 'Per DM CLR: Please review Con Med if also used for AE# 2 COVID-19 as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' answered with 'Correct as entered; it's for prevention of blood clots.' (Site from DM).	Junlin Long (b) (4) (b) (4)	06 Apr 2021 15:57:10
User opened query 'Per DM CLR: Please review Con Med if also used for AE# 2 COVID-19 as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 13:57:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'prevention of blood clots'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '40'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
User entered '1'	System	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
User entered '1'	System	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:47
User entered '804 (804)'	System	24 Feb 2021 18:43:31

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Feb 2021 06:30:07
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 Feb 2021 06:30:07
Data point term sent to Coder	System	24 Feb 2021 18:45:08
User entered 'lasix'	(b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'bilateral lower extremity edema'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '20'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
User entered '2'	System	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
User entered '1'	System	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:52
User entered '804 (804)'	System	24 Feb 2021 18:44:47

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN [GUAIFENESIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 11:28:25
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 11:28:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
Data point term sent to Coder	System	22 Mar 2021 12:44:31
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:44:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN [GUAIFENESIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:10:41
Data point term sent to Coder	System	18 Mar 2021 12:14:24
Coding entries removed.	(b) (4), (b) (6)	18 Mar 2021 12:14:02
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN [GUAIFENESIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 18:49:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 18:49:00
Data point term sent to Coder	System	24 Feb 2021 18:48:13
User entered 'Robitussin'	(b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:56
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:44:20
User entered 'COVID-19' reason for change: New Information	Junlin Long (b) (4)	22 Mar 2021 12:44:20
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 05:54:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:14:08
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 12:14:02
User entered 'worsening of covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 12:14:02
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:42:58
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'cough'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '200'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'every 4 hours as needed'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
User entered empty.	System	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
User entered empty.	System	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:14
User entered empty.	System	24 Feb 2021 18:47:44

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User closed query 'Per DM CLR: Con Med HUMALOG was added on 7 FEB 2021. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:49:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:30:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:30:44
Query 'Per DM CLR: Con Med HUMALOG was added on 7 FEB 2021. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' answered with 'updated AE log.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:30:14
Data point term sent to Coder	System	17 Mar 2021 16:30:12
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 16:30:08
User opened query 'Per DM CLR: Con Med HUMALOG was added on 7 FEB 2021. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:03:51
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 18:50:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 18:50:01
Data point term sent to Coder	System	24 Feb 2021 18:49:14
User entered 'humalog'	(b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:30:08
User entered 'worsening hyperglycemia' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:30:08
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'diabetes'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:41:49
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
User closed query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 10:24:36
Query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dose has been updated to unknown.' (Site from DM).	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:32:11
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:31:57
Signature has been broken.	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:31:57
User entered 'unknown' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	12 Apr 2021 17:31:57
User opened query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 13:57:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'sliding scale'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:49:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:49:06
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:49:06
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:48:51
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:41:49
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	12 Apr 2021 17:31:57
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	12 Apr 2021 17:31:57
User entered 'unknown' reason for change: Per	(b) (4)	
Query Resolution	Junlin Long (b) (4)	12 Apr 2021 17:31:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'sliding scale' reason for change: Data	(b) (4)	
Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:49:06
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 12:51:12
User entered 'other (OTHER)'	(b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Per CDM: Please note there is an available option for "Four Times Daily" in the Frequency Field. Please confirm if this would be a better choice instead of "Other". Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 04:46:27
Query 'Per CDM: Please note there is an available option for "Four Times Daily" in the Frequency Field. Please confirm if this would be a better choice instead of "Other". Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 12:51:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 12:51:12
User opened query 'Per CDM: Please note there is an available option for "Four Times Daily" in the Frequency Field. Please confirm if this would be a better choice instead of "Other". Thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 18:40:21
User entered '4 times daily'	(b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
User entered '4'	System	08 Mar 2021 12:51:12
User entered empty.	System	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
User entered '1'	System	08 Mar 2021 12:51:12
User entered empty.	System	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:23
User entered '804 (804)'	System	08 Mar 2021 12:51:12
User entered empty.	System	24 Feb 2021 18:48:51

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL, PRODUCTSYNONYM: ISOVUE 300 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Feb 2021 18:52:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:52:00
Data point term sent to Coder	System	24 Feb 2021 18:51:19
User entered 'isovue 300'	(b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'CONTRAST For CTA' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:50:56
User entered 'contrast fro cta'	(b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '65'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
User entered empty.	System	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
User entered empty.	System	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:33
User entered empty.	System	24 Feb 2021 18:50:46

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Feb 2021 18:54:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:54:00
Data point term sent to Coder	System	24 Feb 2021 18:53:23
User entered 'potassium chloride'	(b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'hypokalemia'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:53:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:53:32
User entered '40' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:53:32
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:52:59
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'MEQ' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered '40 meQ'	(b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	24 Feb 2021 18:54:40
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Feb 2021 18:54:40
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Feb 2021 18:52:59
User entered 'once (ONCE)'	(b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:54:40
User entered '7 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
User entered empty.	System	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
User entered empty.	System	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:39
User entered empty.	System	24 Feb 2021 18:52:59

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Feb 2021 17:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:19:32
Data point term sent to Coder	System	24 Feb 2021 18:56:30
User entered 'vancomycin'	(b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:56:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:56:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 18:56:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:55:55
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '1000'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'IVPB'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
User entered empty.	System	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
User entered empty.	System	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:49
User entered empty.	System	24 Feb 2021 18:55:55

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:45:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:45:45
Data point term sent to Coder	System	22 Mar 2021 12:45:31
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:44:48
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:22:57
Data point term sent to Coder	System	02 Mar 2021 18:13:39
Coding entries removed.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:12:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:57:59

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Feb 2021 18:57:59
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	24 Feb 2021 18:57:32
User entered 'VITAMIN C'	(b) (4), (b) (6)	24 Feb 2021 18:56:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:56
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:44:48
User entered 'COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	22 Mar 2021 12:44:48
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'worsening COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	02 Mar 2021 18:12:52
User entered 'COVID-19'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '1000'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User entered '1'	System	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User entered '1'	System	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User entered '804 (804)'	System	24 Feb 2021 18:56:52

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:45:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:45:45
Data point term sent to Coder	System	22 Mar 2021 12:45:31
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:44:56
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:15:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:15:58
Data point term sent to Coder	System	02 Mar 2021 18:13:40
Coding entries removed.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:13:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:59:03

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Feb 2021 18:59:03
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	24 Feb 2021 18:58:36
User entered 'VITAMIN D'	(b) (4), (b) (6)	24 Feb 2021 18:57:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:56
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:44:56
User entered 'COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	22 Mar 2021 12:44:56
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'worsening COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	02 Mar 2021 18:13:04
User entered 'COVID-19'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '50,000'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
User entered empty.	System	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
User entered empty.	System	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:01
User entered empty.	System	24 Feb 2021 18:57:36

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:45:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 12:45:44
Data point term sent to Coder	System	22 Mar 2021 12:45:31
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Mar 2021 12:45:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Mar 2021 13:12:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:02:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:02:08
Data point term sent to Coder	System	02 Mar 2021 18:13:39
Coding entries removed.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:13:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:59:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:59:03
Data point term sent to Coder	System	24 Feb 2021 18:58:36
User entered 'ZINC SULFATE'	(b) (4), (b) (6) (b) (4)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:39:56
Signature has been broken.	Junlin Long (b) (4)	22 Mar 2021 12:45:04
User entered 'COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	22 Mar 2021 12:45:04
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'worsening COVID-19' reason for change: New Information	(b) (4) Junlin Long (b) (4)	02 Mar 2021 18:13:15
User entered 'COVID-19'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '220'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:39:56
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
User entered '1'	System	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
User entered '1'	System	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:05
User entered '804 (804)'	System	24 Feb 2021 18:58:29

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
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 04:55:57
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 04:55:57
Data point term sent to Coder	System	24 Mar 2021 12:53:31
User entered 'oxygen'	Junlin Long (b) (4) (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'No (N)'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'acute hypoxemic respiratory failure secondary to covid-19'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '2'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Other (OTHER)'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'liter'	(b) (4) Junlin Long (b) (4) (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'as needed (PRN)'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Nasal (NASAL)'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered empty.	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '6 Feb 2021'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '0'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '9 Feb 2021'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'No (N)'	Junlin Long (b) (4)	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User entered empty.	System	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User entered empty.	System	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User entered empty.	System	24 Mar 2021 12:53:11

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:05:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:05:52
Data point term sent to Coder	System	07 Apr 2021 16:04:49
User entered 'furosemide'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'bilateral lower extremity edema'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered '40'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered '9 Feb 2021'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered '4 Mar 2021'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User entered '1'	System	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User entered '1'	System	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:23
User entered '804 (804)'	System	07 Apr 2021 16:04:19

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:06:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:06:39
Data point term sent to Coder User entered 'levothyroxine'	System Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:52 07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'hypothyroidism'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered '25'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'ug (ug)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered '12 Mar 2021'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:17:34
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 16:05:05

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:11:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Yes (Y)'	Junlin Long	04 Feb 2021 16:51:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	04 Feb 2021 16:51:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Dec 2020 16:50:13

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 16:56:42

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'convalescent plasma'	Junlin Long (b) (4)	04 Feb 2021 16:56:42

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Adverse Event (AE)'	Junlin Long (b) (4)	04 Feb 2021 16:56:42

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long	04 Feb 2021 16:56:42

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 16:57:04

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'ekg'	Junlin Long (b) (4)	04 Feb 2021 16:57:04

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Feb 2021 16:57:04

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:57:04

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '29 Jan 2021'	Junlin Long (b) (4)	04 Feb 2021 16:57:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'chest x-ray'	Junlin Long (b) (4)	04 Feb 2021 16:57:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Feb 2021 16:57:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered empty.	Junlin Long (b) (4)	04 Feb 2021 16:57:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:10

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'EKG'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:10

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:10

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:10

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '06 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 19:01:57
User entered '09 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 18:59:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '07 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:55

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:55

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:55

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:59:55

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:00:38

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'CTA CHEST WITH CONTRAST'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:00:38

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:00:38

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:32
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:00:38

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:01:02

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'ECHOCARDIOGRAM'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:01:02

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:01:02

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:01:02

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:53:49

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'complete metabolic panel'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:53:49

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:53:49

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:53:49

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'SARS-COV-2RNA TEST'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:22

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:47

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'D-DIMER LAB'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:47

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:47

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:54:47

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:03

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'PT LAB'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:03

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:03

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:03

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:17

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'INR LAB'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:17

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:17

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:17

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:39

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'CRP LAB'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:39

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:39

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:40:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:55:39

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '6 Feb 2021'	Junlin Long (b) (4)	24 Mar 2021 12:49:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'complete metabolic panel'	Junlin Long (b) (4)	24 Mar 2021 12:49:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	24 Mar 2021 12:49:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered empty.	Junlin Long (b) (4)	24 Mar 2021 12:49:34

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '6 Feb 2021'	Junlin Long (b) (4)	24 Mar 2021 12:49:51

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'crp lab'	Junlin Long (b) (4)	24 Mar 2021 12:49:51

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	24 Mar 2021 12:49:51

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered empty.	Junlin Long (b) (4)	24 Mar 2021 12:49:51

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:35
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '6 Feb 2021'	Junlin Long (b) (4)	24 Mar 2021 12:50:09

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:35
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'lactic acid lab'	Junlin Long (b) (4)	24 Mar 2021 12:50:09

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:35
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	24 Mar 2021 12:50:09

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:35
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered empty.	Junlin Long (b) (4)	24 Mar 2021 12:50:09

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:11:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:39
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '6 Feb 2021'	Junlin Long (b) (4)	24 Mar 2021 12:50:23

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:11:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:39
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'd-dimer lab'	Junlin Long (b) (4)	24 Mar 2021 12:50:23

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:11:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:39
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	24 Mar 2021 12:50:23

US3622142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:11:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:39
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:03
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered empty.	Junlin Long (b) (4)	24 Mar 2021 12:50:23

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '03/Feb/2021 12:12'	(b) (4) System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:11:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '05/Feb/2021 09:39'	(b) (4) System	05 Feb 2021 14:39:26

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:11:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:07:45
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 14:39:26

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '08/Feb/2021 14:07'	(b) (4) System	08 Feb 2021 14:07:57

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:11:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:35:31
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:07:57

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
User entered '12/Feb/2021 16:35'	(b) (4) System	12 Feb 2021 16:35:57

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:11:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 15:03:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:35:57

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
User entered '19/Feb/2021 10:03'	(b) (4) System	19 Feb 2021 15:03:42

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:11:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:06:43
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 15:03:42

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:48:12
User entered '24/Feb/2021 09:16'	System	24 Feb 2021 14:16:59

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:11:43

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.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:48:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 21:18:32
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 14:16:59

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:48:12
User entered '26/Feb/2021 16:18'	System	26 Feb 2021 21:18:47

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:11:43

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.	Susanne Doblecki-Lewis	05 Mar 2021 21:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:48:12
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 21:18:47

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'USA-US085-2021-MRNA-1273-P301000009'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Yes (Y)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'No (N)'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Susanne'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Doblecki-Lewis'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '1120 NW 14th Street'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'Miami'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered 'FL'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:12:45
User entered '33136'	System	03 Feb 2021 17:12:30

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:12
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:39:07
User entered 'US'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Mar 2021 14:55:28
User entered '7'	System	26 Feb 2021 21:18:47
Signature has been broken.	System	24 Feb 2021 14:16:59
User entered '6'	System	24 Feb 2021 14:16:59
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:10:55
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:42
User entered '5'	System	19 Feb 2021 15:03:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:16
	(b) (4)	
Signature has been broken.	System	12 Feb 2021 16:35:57
User entered '4'	System	12 Feb 2021 16:35:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered '3'	System	08 Feb 2021 14:07:57
User entered '2'	System	05 Feb 2021 14:39:26
User entered '1'	System	03 Feb 2021 17:12:54

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:43
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered '23/Mar/2021 10:55'	(b) (4) System	23 Mar 2021 14:55:28

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:11:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:43
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:55:28

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'USA-US085-2021-MRNA-1273-P301000012'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Yes (Y)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Yes (Y)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Susanne'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Doblecki-Lewis'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered '1120 NW 14th Street'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Miami'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'FL'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered '33136'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'US'	(b) (4) System	09 Feb 2021 17:32:29

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'I'	(b) (4) System	09 Feb 2021 17:32:29

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'USA-US085-2021-MRNA-1273-P301000012'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Yes (Y)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Yes (Y)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'No (N)'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Susanne'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Doblecki-Lewis'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered '1120 NW 14th Street'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'Miami'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered 'FL'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:11
User entered '33136'	System	09 Feb 2021 17:30:27

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'US'	(b) (4) System	09 Feb 2021 17:32:29

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
	(b) (4)	
User entered 'I'	System	09 Feb 2021 17:32:29

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:11:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered '09/Feb/2021 12:32'	(b) (4) System	09 Feb 2021 17:32:29

US3622142

Folder: SAE USA-US085-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:11:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 13:48:39
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:03:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:32:29