

US3272144 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:51:48

All time stamps listed in this document are displayed in GMT

**US3272144**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:51:48**

[Participant ID](#)

US3272144

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

US3272144

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3272144

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:48

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3272144

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:48

Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3272144

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:51:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3272144

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:48

Were any significant conditions reported?

Yes ☒

No ☐

US3272144

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:48

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3272144

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:48

Condition	HEMORRHOIDECTOMY
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3272144

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:48

Condition	HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3272144

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:48

Condition	CAT ALLERGY
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3272144

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:40
Height ( <i>xxx.x</i> )	187 cm
Weight ( <i>xxx.x</i> )	142.3 kg
BMI ( <i>xxx.x</i> )	40.69319 kg/m <sup>2</sup>
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)	

US3272144

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

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.*

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

**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**

FARMER, CHURCH, GROCERY SHOPPING

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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

v6.020 DTW (1102)

18 of 2689

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

US3272144

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3272144

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:48

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 143836

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 ☒

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:51:48**

Height	ND - Not Done
Weight	ND - Not Done

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:48

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)	14 AUG 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:40
Temperature (xxx.x)	37 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG



US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	11:46 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:46
Temperature (xxx.x)	37 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3272144

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3272144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	14 AUG 2020
What was the treatment time? (00:00-23:59)	11:11 (24 HR)
Treatment Date and Time (derived)	14 AUG 2020 11:11
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3272144

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	14 AUG 2020
Collection time ( <i>00:00-23:59</i> )	10:05 (24 HR)
Collection date and time (derived)	14 AUG 2020 10:05

US3272144

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 11:44

PC Open Date & Time

14 AUG 2020 11:31

PC Close Date & Time

14 AUG 2020 14:01

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

PC Time Stamp	15 AUG 2020 07:14
PC Open Date & Time	14 AUG 2020 14:56
PC Close Date & Time	15 AUG 2020 11:59



US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 15 AUG 2020 20:03

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:48

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.6 °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

16 AUG 2020 21:43

---

PC Open Date & Time

16 AUG 2020 12:00

---

PC Close Date & Time

17 AUG 2020 11:59

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US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:48

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 00:00

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:48

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**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 ☒

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

Yes ☐

No ☒

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

---

PC Time Stamp 19 AUG 2020 13:18

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

---

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:48

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 20:28

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 11:44

PC Open Date & Time

14 AUG 2020 11:31

PC Close Date & Time

14 AUG 2020 14:01

US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

**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

15 AUG 2020 07:15

PC Open Date & Time

14 AUG 2020 14:56

PC Close Date & Time

15 AUG 2020 11:59



US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:48

**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

15 AUG 2020 20:04

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:48

**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

16 AUG 2020 21:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:48

**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

18 AUG 2020 00:00

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:48

**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

19 AUG 2020 13:18

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:48

**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

20 AUG 2020 20:28

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

**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 ☐

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 11:45
PC Open Date & Time	14 AUG 2020 11:31
PC Close Date & Time	14 AUG 2020 14:01



US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

**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 ☐

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 07:16
PC Open Date & Time	14 AUG 2020 14:56
PC Close Date & Time	15 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:48

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:05
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:48

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 21:43
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:48

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 ☐

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:48

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 13:18
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:48

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 ☒

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:48

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 20:28
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

**US3272144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

Was Contact Attempted?

Yes ☒

No ☐

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

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272144

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3272144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

*Was Contact Attempted?*

Yes ☒

No ☐

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

28 AUG 2020

*Please select one status for the follow-up contact*

Contact Made ☒

Contact Not Made ☐

*Comments*

*If Contact Not Made, please provide Comments*

US3272144

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3272144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

Was Contact Attempted?

Yes ☒

No ☐

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

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272144

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272144

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:18
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:39
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3272144

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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



US3272144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 12:05

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

US3272144

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	11 SEP 2020
Collection time ( <i>00:00-23:59</i> )	11:37 (24 HR)
Collection date and time (derived)	11 SEP 2020 11:37

US3272144

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:48

Collection date ( <i>dd MMM yyyy</i> )			11 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	11 SEP 2020 11:30
Nasopharyngeal Swab 2	No		

US3272144

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 11 SEP 2020 12:42

PC Open Date & Time 11 SEP 2020 12:25

PC Close Date & Time 11 SEP 2020 14:55

US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	11 SEP 2020 21:23
PC Open Date & Time	11 SEP 2020 15:50
PC Close Date & Time	12 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:48

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**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

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

12 SEP 2020 22:21

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PC Open Date & Time

12 SEP 2020 12:00

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PC Close Date & Time

13 SEP 2020 11:59

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US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:48

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

13 SEP 2020 23:09

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:48

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**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

97.8 °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

15 SEP 2020 00:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:48

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

15 SEP 2020 20:43

---

PC Open Date & Time

15 SEP 2020 12:00

---

PC Close Date & Time

16 SEP 2020 11:59

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US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:48

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.5 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

17 SEP 2020 07:54

---

PC Open Date & Time

16 SEP 2020 12:00

---

PC Close Date & Time

17 SEP 2020 11:59

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US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:48

**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**

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 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:34

PC Open Date & Time

11 SEP 2020 12:25

PC Close Date & Time

11 SEP 2020 14:55

US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

**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

11 SEP 2020 21:24

PC Open Date & Time

11 SEP 2020 15:50

PC Close Date & Time

12 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:21

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 23:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:48

**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

15 SEP 2020 00:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 20:43

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 07:55

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:48

**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 ☐

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

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

**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 ☐

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 12:33
PC Open Date & Time	11 SEP 2020 12:25
PC Close Date & Time	11 SEP 2020 14:55

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

**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 ☐

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:24
PC Open Date & Time	11 SEP 2020 15:50
PC Close Date & Time	12 SEP 2020 11:59



US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:48

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:22
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 23:10
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:43
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59



US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:48

**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 ☒

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:48

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 07:55
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

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

**US3272144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

Was Contact Attempted?

Yes ☒

No ☐

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

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272144

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272144

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:48

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272144

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272144

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:48

Was Contact Attempted?

Yes ☒

No ☐

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

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272144

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272144

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3272144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	06 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	09:34 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 09:34
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272144

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3272144

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	06 OCT 2020
Collection time ( <i>00:00-23:59</i> )	09:38 (24 HR)
Collection date and time (derived)	06 OCT 2020 09:38

US3272144

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272144

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 13:15:48

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59



US3272144

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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

21 OCT 2020 14:28:15

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3272144

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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

28 OCT 2020 00:01:32

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3272144

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 13:56:43
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 OCT 2020 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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18 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 OCT 2020 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 NOV 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2020 23:59
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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

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

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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22 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2020 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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29 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 DEC 2020 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59
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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 FEB 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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07 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 FEB 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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28 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAR 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 MAR 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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11 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 APR 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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18 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 APR 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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25 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 APR 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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 <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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 AUG 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 NOV 2021 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 NOV 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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="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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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 ☐



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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 ☐



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

**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 ☐

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3272144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:48

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"/>

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

20 OCT 2022 23:59

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**US3272144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

Was Contact Attempted?

Yes ☒

No ☐

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

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3272144

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3272144**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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*

**US3272144**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:51:48

Date of Contact	4 NOV 2020
Time of Contact	12:42
Date and Time of Contact (derived)	4 NOV 2020 12:42
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	341 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	345 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="radio"/>
	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 checked="" type="radio"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	349 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	353 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:48

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:48

	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	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	357 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:48

	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 type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	101.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	361 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:48

	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	365 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:48

	Severe	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	100.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	369 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:48

Symptom Day

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	373 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:48

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" 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 checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	377 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	381 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:48

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:48

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	101.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	385 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:48

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:48

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	100.2 F	
Chills	None <input type="checkbox"/>	
	Mild <input checked="" type="radio"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Cough	None <input type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input checked="" type="radio"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Shortness of Breath	None <input type="checkbox"/>	
	Mild <input checked="" type="radio"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Difficulty Breathing	None <input type="checkbox"/>	
	Mild <input checked="" type="radio"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Fatigue	None <input checked="" type="radio"/>	
v6.020 DTW (1102)	389 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:48

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:48

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" 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 checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	393 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:51:48

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	97.0 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 type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	397 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:51:48

	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	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	36.6 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	401 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:51:48

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

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

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

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

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:51:48

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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:51:48

	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	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" 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 checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	405 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:51:48

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

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

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

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

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:51:48

[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"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:51:48

	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	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	409 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:51:48

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

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

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

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

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

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

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:51:48

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 type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:51:48

	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	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	413 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:51:48

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 type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:51:48

	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	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	417 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:51:48

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 type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:51:48

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	421 of 2689	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:51:48

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

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

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

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

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

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

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:51:48

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



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:48

Date of Visit	4 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	4 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below _____	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date \_\_\_\_\_ 11 NOV 2020

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_ 92 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

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

Start Date \_\_\_\_\_

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

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

**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 \_\_\_\_\_

Hepatic Dysfunction? Yes ☐ No ☒

Start Date \_\_\_\_\_

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒  
No ☐

Date of Assessment 13 NOV 2020

Radiographical Evidence Yes ☒  
No ☐

Date of Assessment 13 NOV 2020

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

Start Date

End Date

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 10:51:48**

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

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**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Generated On: 26 Nov 2020 10:51:48**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	6 NOV 2020
Day 5	Yes	8 NOV 2020
Day 7	Yes	10 NOV 2020
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3272144

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3272144

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	14:55 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 14:55
Height ( <i>xxx.x</i> )	187 cm
Weight ( <i>xxx.x</i> )	142.6 kg
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	87 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3272144

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 NOV 2020

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

US3272144

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:51:48

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

4 NOV 2020

**US3272144**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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 \_\_\_\_\_

US3272144

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

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.*

**US3272144**

**Folder: Convalescence Visit Day 28 (1)**

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

**Generated On: 26 Nov 2020 10:51:48**

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

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

US3272144

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:48

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

AEID	USA-US070-2020-MRNA-1273-P30 1000017
Adverse event	COVID 19 ILLNESS
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)	2 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	12 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	19 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	439 of 2689



US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

---

FIRST SYMPTOMS 2NOV2020,  
CONFIRMED COVID  
CONFIRMED 10NOV2020.  
SYMPTOMS WORSENING  
11NOV2020, CONTACTED PCP  
AND WAS SENT RX COUGH  
SYRUP. APPOINTMENT  
12NOV2020, ADMITTED TO  
GENERAL OBSERVATION.  
STABLE, NO O2 SUPPORT  
CURRENTLY. ACETAMINOPHEN  
AND ENOXAPARIN WHILE  
UNDER OBSERVATION. HE  
RETURNED HOME FROM THE  
HOSPITAL 13NOV2020 WITH NO  
NEW MEDICATIONS.

OXYGENATION REMAINED  
AROUND 92% AND BEGAN  
HAVING OCCURRENCES OF  
BRONCHOSPASM. RETURNED  
TO ED 16NOV2020 WITH  
HYPOXIA WITH SATURATIONS  
80% AND SOB. WAS ADMITTED  
TO GENERAL FLOOR  
16NOV2020. WAS GIVEN  
DEXAMETHASONE 6MG IV BID  
STARTED 16NOV2020 UNTIL  
18NOV2020, LEVOFLOXACIN  
500 MG PO STARTED  
17NOV2020, AND REMDESEVIR  
200 MG IV X 1 AND THEN 100  
MG IV DAILY. GIVEN 25 MG PO  
TRAMADOL FOR A HEADACHE  
SECONDARY TO HYPOXIA ON  
17NOV2020. WAS ON 2L/NC  
DURING NIGHT, BUT WAS

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

---

ROOM AIR WHILE AWAKE.  
GIVEN LACTOBACILLUS 1  
BILLION UNITS PO X 1 ON  
17NOV2020 FOR REPEATED  
EPISODES OF DIARRHEA.

RELEASED FROM HOSPITAL  
CARE 19NOV2020. ON ROOM  
AIR, SATURATIONS AT 98-99%,  
GIVEN PRESCRIPTION FOR  
ZINC SULFATE 220 MG PO  
DAILY, VITAMIN D3 2000 IU PO  
DAILY, LEVOFLOXACIN,  
DEXAMETHASONE PO 6 MG  
DAILY, AND VITAMIN C 500 MG  
PO DAILY. ALBUTEROL  
INHALER 180 MCG TID,  
STARTED 18NOV2020.  
INSTRUCTIONS TO FOLLOW UP  
WITH PCP AS NEEDED.

---

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

---

US3272144

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:48

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	

US3272144

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:48

Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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 type="radio"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	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)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:51:48

---

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

Yes ☒

No ☐

---

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

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US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	CLONAZEPAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INSOMNIA
Dose per administration	1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:48

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

Indication	NUTRITIONAL HEALTH
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify

Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>
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US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>



US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:48

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

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date ( <i>dd MMM yyyy</i> )		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> ) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID 19 ILLNESS
Dose per administration	325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		2 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	PSEUDOEPHEDRINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID 19 ILLNESS
Dose per administration	120
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		7 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	ENOXAPARIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DEEP VEIN THROMBOSIS 2ND TO COVID 19 ILLNESS
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:48

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	HALLS COUGH DROPS
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID 19
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	LOZENGE
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:48

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	REMDESIVIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID 19
Dose per administration	200
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:48

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	REMDESEVIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID 19
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:48

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)	17 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID 19
Dose per administration	6
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:48

	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)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	TRAMADOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHE SECONDARY TO HYPOXIA
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:48

	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)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	LEVOFLOXACIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID 19, PREVENTION OF SECONDARY PNEUMONIA
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:48

	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)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID 19
Dose per administration	6
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:48

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	VITAMIN C
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	IMMUNE SUPPLEMENT
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:51:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	VITAMIN D3
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	IMMUNE SUPPLEMENT
Dose per administration	2000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:51:48

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	ZINC SULFATE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	IMMUNE SUPPLEMENT
Dose per administration	220
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:51:48

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:51:48

Name of Medication	LACTOBACILLUS
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIARRHEA
Dose per administration	1000000
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	UNITS
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:51:48

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:51:48

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:51:48

Procedure/Surgery date ( <i>dd MMM yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
16 NOV 2020	CHEST X-RAY	Adverse Event	
17 NOV 2020	CHEST X-RAY	Adverse Event	
18 NOV 2020	CHEST X-RAY	Adverse Event	



US3272144

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:51:48

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3272144

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:51:48

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 ☐

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:48

SAEID	USA-US070-2020-MRNA-1273-P301000017
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:48

SAEID	USA-US070-2020-MRNA-1273-P301000017
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/NOV/2020 21:28
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

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:51:48

SAEID	USA-US070-2020-MRNA-1273-P301000017
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:33
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

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:51:48

SAEID	USA-US070-2020-MRNA-1273-P301000017
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/NOV/2020 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

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:51:48

SAEID	USA-US070-2020-MRNA-1273-P301000017
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/NOV/2020 14:47
<b>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.</b>	<input checked="" type="checkbox"/> True

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:51:48

SAEID	USA-US070-2020-MRNA-1273-P301000017
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 11:30
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

US3272144 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

**US3272144**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:51:48**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3272144'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Aug 2020 15:25:10

**US3272144**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:23:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:08:59

**US3272144**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:23:40
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:25:11

**US3272144**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:23:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 18:08:59

**US3272144**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Aug 2020 18:08:59

US3272144

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:25:12

US3272144

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:48

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 16:09:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 16:09:19
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	15 Aug 2020 16:09:19
User entered '29' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 16:09:19
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:38:35
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	14 Aug 2020 16:38:35
User entered empty.	Ashley Bell (b) (4)	14 Aug 2020 16:38:35



**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	15 Aug 2020 16:09:19
User entered empty.	System	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '29'	System	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered 'Male (M)'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered 'I'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered '0'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered '0'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered '0'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35



**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered '0'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered '0'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered empty.	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered '0'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:48**

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:00
User entered '0'	Ashley Bell (b) (4)	14 Aug 2020 16:38:35

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:06
User entered '14 Aug 2020'	Ashley Bell (b) (4)	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Aug 2020 16:38:46



**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:06
User entered 'Amendment 2 (2)'	Ashley Bell (b) (4)	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:06
User entered 'Yes (Y)'	Ashley Bell (b) (4)	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:06
User entered empty.	Ashley Bell (b) (4)	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:06
User entered empty.	Ashley Bell (b) (4)	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:06
User entered 'No (N)'	Ashley Bell (b) (4)	14 Aug 2020 16:38:46

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:25:11

**US3272144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:48**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:38:55

**US3272144**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:11
User entered 'Yes (Y)'	Ashley Bell (b) (4)	14 Aug 2020 16:38:55



**US3272144**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:51:48**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:26:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:09:20

US3272144

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 18:11:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 18:11:16
Data point term sent to Coder	System	14 Aug 2020 18:10:00
User entered 'insomnia'	(b) (4), (b) (6)	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	14 Aug 2020 18:09:45



**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2015'	System	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:09:45

**US3272144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:09:45

US3272144

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:48

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:12:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:12:17
Data point term sent to Coder	System	14 Aug 2020 18:11:01
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	(b) (4), (b) (6)	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:10:06



**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '1995'	System	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:10:06

**US3272144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:10:06

US3272144

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:48

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:12:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:12:17
Data point term sent to Coder	System	14 Aug 2020 18:11:01
User entered 'seasonal allergies'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	(b) (4), (b) (6)	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:10:24



**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '1995'	System	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:10:24

**US3272144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:10:24

US3272144

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:12:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:12:16
Data point term sent to Coder	System	14 Aug 2020 18:11:01
User entered 'vasectomy'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 18:10:56



**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 18:10:56

**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:10:56

**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:10:56

**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 18:10:56

**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:10:56

**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	14 Aug 2020 18:10:56

**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2019'	System	14 Aug 2020 18:10:56

**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	14 Aug 2020 18:10:56



**US3272144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2019'	System	14 Aug 2020 18:10:56

US3272144

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:48

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:51:10
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 22:19:13
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:44:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 18:14:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 18:14:17
Data point term sent to Coder	System	14 Aug 2020 18:13:05
User entered 'hemorrhoidectomy'	(b) (4), (b) (6)	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	(b) (4), (b) (6)	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	(b) (4), (b) (6)	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	14 Aug 2020 18:12:27



**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2016'	System	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	14 Aug 2020 18:12:27

**US3272144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2016'	System	14 Aug 2020 18:12:27

US3272144

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:48

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Allergy to grains - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 05:48:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 05:48:10
Data point term sent to Coder	System	14 Aug 2020 18:13:06
User entered 'wheat allergy'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:12:55



**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2019'	System	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:12:55

**US3272144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:12:55

US3272144

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:15:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:15:22
Data point term sent to Coder	System	14 Aug 2020 18:14:06
User entered 'severe obesity'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:13:15



**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:13:15

**US3272144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:13:15

US3272144

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 22:21:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 22:21:50
Data point term sent to Coder	System	25 Sep 2020 22:20:41
User entered 'Hemorrhoids'	(b) (4), (b) (6)	25 Sep 2020 22:20:10



**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	(b) (4), (b) (6)	25 Sep 2020 22:20:10

**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 22:20:10

**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 22:20:10

**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	(b) (4), (b) (6)	25 Sep 2020 22:20:10

**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 22:20:10

**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	25 Sep 2020 22:20:10

**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2013'	System	25 Sep 2020 22:20:10

**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	25 Sep 2020 22:20:10



**US3272144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2016'	System	25 Sep 2020 22:20:10

US3272144

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:48

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergic to cats - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:23:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:23:39
Data point term sent to Coder	System	04 Nov 2020 22:22:45
User entered 'cat allergy'	(b) (4), (b) (6) (b) (4)	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	(b) (4), (b) (6)	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	04 Nov 2020 22:22:45



**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '2016'	System	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:22:45

**US3272144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:22:45

US3272144

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 22:11:12
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 21:58:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered '14 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered '09:40' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '09:40'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 09:40'	System	25 Sep 2020 21:58:53
User entered empty.	System	16 Sep 2020 15:36:26
User entered '14 Aug 2020 09:40'	System	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered '187' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '187' cm	(b) (4), (b) (6)	14 Aug 2020 18:14:34
DataPoint set to visible.	System	14 Aug 2020 16:38:55



**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered '142.3' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '142.3' kg	(b) (4), (b) (6)	14 Aug 2020 18:14:34
DataPoint set to visible.	System	14 Aug 2020 16:38:55

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

**BMI (xxx.x)**

Audit	User	Time (GMT)
User entered '40.69319'	System	25 Sep 2020 21:58:53
User entered empty.	System	16 Sep 2020 15:36:26
User entered '40.7'	System	14 Aug 2020 18:14:34
DataPoint set to visible.	System	14 Aug 2020 16:38:55

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	25 Sep 2020 21:58:53
User entered empty.	System	16 Sep 2020 15:36:26
User entered 'kg/m2'	System	14 Aug 2020 18:14:34
DataPoint set to visible.	System	14 Aug 2020 16:38:55

US3272144

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 22:11:15
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 21:59:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:23
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:23
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:36:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 21:07:49
User entered '37' C	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered 'Other (Other)'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered 'temporal'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '78'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 21:58:53
User entered empty.	System	16 Sep 2020 15:36:26
User entered 'bpm'	System	14 Aug 2020 18:14:34



US3272144

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '18'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 21:58:53
User entered empty.	System	16 Sep 2020 15:36:26
User entered 'breaths/min'	System	14 Aug 2020 18:14:34

US3272144

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '126'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 21:58:53
User entered empty.	System	16 Sep 2020 15:36:26
User entered 'mmHg'	System	14 Aug 2020 18:14:34

US3272144

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 21:58:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:36:26
User entered '78'	(b) (4), (b) (6)	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 21:58:53
User entered empty.	System	16 Sep 2020 15:36:26
User entered 'mmHg'	System	14 Aug 2020 18:14:34

**US3272144**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 19:17:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:14:58

US3272144

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:27:59
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:17:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 19:17:06
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 17:49:01
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:14:58



US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23



US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

**US3272144**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

**US3272144**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:51:48**

**Other**

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

**US3272144**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[Specify](#)

Audit	User	Time (GMT)
User entered 'farmer, church, grocery shopping'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

**No Risk Identified**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:16:23



US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

**US3272144**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:51:48**

**Other**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:16:23

US3272144

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:48

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:16:23

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:16:34

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:07
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:16:34

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 18:16:34



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Aug 2020 18:16:34

US3272144

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:25:24

US3272144

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:48

What was the participant's randomization number?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:32:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:32:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 15:25:24
User entered '143836' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:25:24

US3272144

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:25:24

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:58

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:58

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:16:58

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:58



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:48**

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:16:58

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 21:25:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:17:12

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:48

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:09:21
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:16:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:16:49
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:54:44
User entered '187' cm	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:51:48**

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:16:49
User entered '142.3' kg	(b) (4), (b) (6)	14 Aug 2020 18:19:50

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:48

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:09:21
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:16:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:16:49
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:54:44
User entered '187' cm	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:51:48**

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:16:49
User entered '142.3' kg	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:19:50



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '09:40'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 09:40'	System	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '37' C	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered 'Other (Other)'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered 'temporal'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '78'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 18:19:50



US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '18'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 18:19:50

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '126'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '78'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 18:19:50

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:48

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:09:21
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:16:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:16:49
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:54:44
User entered '187' cm	(b) (4), (b) (6)	14 Aug 2020 18:19:50

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:48

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:16:49
User entered '142.3' kg	(b) (4), (b) (6)	14 Aug 2020 18:19:50



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 17:24:06
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'confirm correct ' (Site from System).	Ashley Bell (b) (4)	15 Aug 2020 14:13:20
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 18:19:50
User entered '11:46'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:46'	System	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '37' C	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered 'Other (Other)'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered 'temporal'	(b) (4), (b) (6)	14 Aug 2020 18:19:50



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '77'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 18:19:50

US3272144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '16'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '119'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:28:25
User entered '78'	(b) (4), (b) (6)	14 Aug 2020 18:19:50

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 18:19:50



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:19:57

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:32
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:19:57

US3272144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:40
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	15 Aug 2020 15:29:16
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	15 Aug 2020 15:29:16
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Aug 2020 16:39:11
User entered 'Yes (Y)'	Ashley Bell (b) (4)	14 Aug 2020 16:39:11

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:40
User entered empty.	Ashley Bell (b) (4)	14 Aug 2020 16:39:11

US3272144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:40
User entered empty.	Ashley Bell (b) (4)	14 Aug 2020 16:39:11

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 16:39:11

US3272144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:40
User entered '14 Aug 2020'	Ashley Bell (b) (4)	14 Aug 2020 16:39:11

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:40
User entered '11:11'	Ashley Bell (b) (4)	14 Aug 2020 16:39:11



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:11'	System	14 Aug 2020 16:39:11

US3272144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:40
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 15:29:16
User entered empty.	Ashley Bell (b) (4)	14 Aug 2020 16:39:11

US3272144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:40
User entered 'ONCE'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:20:15

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:48
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:20:15

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:29:48
User entered '10:05'	(b) (4), (b) (6)	14 Aug 2020 18:20:15

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:05'	System	14 Aug 2020 18:20:15



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 10:51:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:30:04
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 18:20:38

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Aug 2020 18:20:38

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:30:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:20:38

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:30:04
User entered '10:00'	(b) (4), (b) (6)	14 Aug 2020 18:20:38

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:00'	System	14 Aug 2020 18:20:38

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Aug 2020 18:20:38

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:30:04
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:20:38

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:30:04
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:20:38



**US3272144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:20:38

US3272144

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:20:43

**US3272144**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 18:20:43

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:43:47', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd50dfebb-f606-43e7-a082-cf0fe540a780'	System	14 Aug 2020 16:44:13
User entered 'Yes (Y)'	System	14 Aug 2020 16:44:13

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:43:51', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd50dfebb-f606-43e7-a082-cf0fe540a780'	System	14 Aug 2020 16:44:13
User entered '98.7'	System	14 Aug 2020 16:44:13

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:43:58', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd50dfebb-f606-43e7-a082-cf0fe540a780'	System	14 Aug 2020 16:44:13
User entered 'No (N)'	System	14 Aug 2020 16:44:13

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:44:09', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd50dfebb-f606-43e7-a082-cf0fe540a780'	System	14 Aug 2020 16:44:13
User entered '14 Aug 2020 11:44'	System	14 Aug 2020 16:44:13



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:31'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:01'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:14:26', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'aa648904-260d-4d84-9c86-5acbbf741a4f'	System	15 Aug 2020 12:14:44
User entered 'Yes (Y)'	System	15 Aug 2020 12:14:44

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:14:32', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'aa648904-260d-4d84-9c86-5acbbf741a4f'	System	15 Aug 2020 12:14:44
User entered '98.9'	System	15 Aug 2020 12:14:44

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:14:38', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'aa648904-260d-4d84-9c86-5acbbf741a4f'	System	15 Aug 2020 12:14:44
User entered 'No (N)'	System	15 Aug 2020 12:14:44

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:14:41', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'aa648904-260d-4d84-9c86-5acbbf741a4f'	System	15 Aug 2020 12:14:44
User entered '15 Aug 2020 07:14'	System	15 Aug 2020 12:14:44

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:56'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 2'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:14', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'f9d28857-0904-4fe2-8879-888dc86a9a5d'	System	16 Aug 2020 01:03:44
User entered 'Yes (Y)'	System	16 Aug 2020 01:03:44

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:18', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'f9d28857-0904-4fe2-8879-888dc86a9a5d'	System	16 Aug 2020 01:03:44
User entered '98.6'	System	16 Aug 2020 01:03:44

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:24', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'f9d28857-0904-4fe2-8879-888dc86a9a5d'	System	16 Aug 2020 01:03:44
User entered 'Yes (Y)'	System	16 Aug 2020 01:03:44

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:36', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'f9d28857-0904-4fe2-8879-888dc86a9a5d'	System	16 Aug 2020 01:03:44
User entered '0'	System	16 Aug 2020 01:03:44

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject inadvertently pushed incorrect button' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 09:30:17
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Aug 2020 01:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:36', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'f9d28857-0904-4fe2-8879-888dc86a9a5d'	System	16 Aug 2020 01:03:44
User entered '1'	System	16 Aug 2020 01:03:44

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:41', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'f9d28857-0904-4fe2-8879-888dc86a9a5d'	System	16 Aug 2020 01:03:44
User entered '15 Aug 2020 20:03'	System	16 Aug 2020 01:03:44



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 3'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:42:52', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0426bc97-efc9-46cc-bdc2-3578c3e0cf38'	System	17 Aug 2020 02:43:08
User entered 'Yes (Y)'	System	17 Aug 2020 02:43:08

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:42:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0426bc97-efc9-46cc-bdc2-3578c3e0cf38'	System	17 Aug 2020 02:43:08
User entered '98.6'	System	17 Aug 2020 02:43:08

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:02', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0426bc97-efc9-46cc-bdc2-3578c3e0cf38'	System	17 Aug 2020 02:43:08
User entered 'No (N)'	System	17 Aug 2020 02:43:08

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:05', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0426bc97-efc9-46cc-bdc2-3578c3e0cf38'	System	17 Aug 2020 02:43:08
User entered '16 Aug 2020 21:43'	System	17 Aug 2020 02:43:08

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 4'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-17T23:59:54', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0ab838b7-78ec-448e-8635-53a4de43c983'	System	18 Aug 2020 05:00:11
User entered 'Yes (Y)'	System	18 Aug 2020 05:00:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:01', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0ab838b7-78ec-448e-8635-53a4de43c983'	System	18 Aug 2020 05:00:11
User entered '98.5'	System	18 Aug 2020 05:00:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:03', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0ab838b7-78ec-448e-8635-53a4de43c983'	System	18 Aug 2020 05:00:11
User entered 'No (N)'	System	18 Aug 2020 05:00:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:06', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '0ab838b7-78ec-448e-8635-53a4de43c983'	System	18 Aug 2020 05:00:11
User entered '18 Aug 2020 00:00'	System	18 Aug 2020 05:00:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 5'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 6'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:08', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ee11b0e3-1270-4d84-93d0-38f1fd2a0ee3'	System	19 Aug 2020 18:18:21
User entered 'No (N)'	System	19 Aug 2020 18:18:21

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:12', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ee11b0e3-1270-4d84-93d0-38f1fd2a0ee3'	System	19 Aug 2020 18:18:21
User entered 'No (N)'	System	19 Aug 2020 18:18:21

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:15', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ee11b0e3-1270-4d84-93d0-38f1fd2a0ee3'	System	19 Aug 2020 18:18:21
User entered '19 Aug 2020 13:18'	System	19 Aug 2020 18:18:21

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 7'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:27:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5eff4694-adf5-48a2-bae2-6ff32108e8d4'	System	21 Aug 2020 01:28:16
User entered 'Yes (Y)'	System	21 Aug 2020 01:28:16

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:02', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5eff4694-adf5-48a2-bae2-6ff32108e8d4'	System	21 Aug 2020 01:28:16
User entered '98.8'	System	21 Aug 2020 01:28:16

US3272144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:05', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5eff4694-adf5-48a2-bae2-6ff32108e8d4'	System	21 Aug 2020 01:28:16
User entered 'No (N)'	System	21 Aug 2020 01:28:16

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:08', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5eff4694-adf5-48a2-bae2-6ff32108e8d4'	System	21 Aug 2020 01:28:16
User entered '20 Aug 2020 20:28'	System	21 Aug 2020 01:28:16

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:44:19', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2616ac4a-4e6c-4cc9-85ca-9fdf0e70a7ec'	System	14 Aug 2020 16:45:02
User entered 'None (1)'	System	14 Aug 2020 16:45:02

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:44:32', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2616ac4a-4e6c-4cc9-85ca-9fdf0e70a7ec'	System	14 Aug 2020 16:45:02
User entered 'No (N)'	System	14 Aug 2020 16:45:02

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:44:41', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2616ac4a-4e6c-4cc9-85ca-9fdf0e70a7ec'	System	14 Aug 2020 16:45:02
User entered 'No (N)'	System	14 Aug 2020 16:45:02

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:44:54', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2616ac4a-4e6c-4cc9-85ca-9fdf0e70a7ec'	System	14 Aug 2020 16:45:02
User entered 'None (1)'	System	14 Aug 2020 16:45:02

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:44:58', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2616ac4a-4e6c-4cc9-85ca-9fdf0e70a7ec'	System	14 Aug 2020 16:45:02
User entered '14 Aug 2020 11:44'	System	14 Aug 2020 16:45:02

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:31'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:01'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:14:51', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5d38094d-65ac-442d-b68b-cd975616965c'	System	15 Aug 2020 12:15:26
User entered 'None (1)'	System	15 Aug 2020 12:15:26

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:14:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5d38094d-65ac-442d-b68b-cd975616965c'	System	15 Aug 2020 12:15:26
User entered 'No (N)'	System	15 Aug 2020 12:15:26

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:02', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5d38094d-65ac-442d-b68b-cd975616965c'	System	15 Aug 2020 12:15:26
User entered 'No (N)'	System	15 Aug 2020 12:15:26

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:17', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5d38094d-65ac-442d-b68b-cd975616965c'	System	15 Aug 2020 12:15:26
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 12:15:26

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:20', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5d38094d-65ac-442d-b68b-cd975616965c'	System	15 Aug 2020 12:15:26
User entered '15 Aug 2020 07:15'	System	15 Aug 2020 12:15:26

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:56'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 2'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:46', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f800c07-b800-4daf-9403-a4ac74a42566'	System	16 Aug 2020 01:04:14
User entered 'None (1)'	System	16 Aug 2020 01:04:14

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:49', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f800c07-b800-4daf-9403-a4ac74a42566'	System	16 Aug 2020 01:04:14
User entered 'No (N)'	System	16 Aug 2020 01:04:14

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:03:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f800c07-b800-4daf-9403-a4ac74a42566'	System	16 Aug 2020 01:04:14
User entered 'No (N)'	System	16 Aug 2020 01:04:14

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:04:07', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f800c07-b800-4daf-9403-a4ac74a42566'	System	16 Aug 2020 01:04:14
User entered 'None (1)'	System	16 Aug 2020 01:04:14

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:04:10', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f800c07-b800-4daf-9403-a4ac74a42566'	System	16 Aug 2020 01:04:14
User entered '15 Aug 2020 20:04'	System	16 Aug 2020 01:04:14

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 3'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:10', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '050d6b2d-ccc6-480c-b518-66382c5d0524'	System	17 Aug 2020 02:43:31
User entered 'None (1)'	System	17 Aug 2020 02:43:31

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:12', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '050d6b2d-ccc6-480c-b518-66382c5d0524'	System	17 Aug 2020 02:43:31
User entered 'No (N)'	System	17 Aug 2020 02:43:31

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:15', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '050d6b2d-ccc6-480c-b518-66382c5d0524'	System	17 Aug 2020 02:43:31
User entered 'No (N)'	System	17 Aug 2020 02:43:31

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:24', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '050d6b2d-ccc6-480c-b518-66382c5d0524'	System	17 Aug 2020 02:43:31
User entered 'None (1)'	System	17 Aug 2020 02:43:31

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:27', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '050d6b2d-ccc6-480c-b518-66382c5d0524'	System	17 Aug 2020 02:43:31
User entered '16 Aug 2020 21:43'	System	17 Aug 2020 02:43:31

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 4'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:10', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '7423ace8-c508-4f90-adba-516ccbe1a822'	System	18 Aug 2020 05:00:25
User entered 'None (1)'	System	18 Aug 2020 05:00:25

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:13', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '7423ace8-c508-4f90-adba-516ccbe1a822'	System	18 Aug 2020 05:00:25
User entered 'No (N)'	System	18 Aug 2020 05:00:25

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:16', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '7423ace8-c508-4f90-adba-516ccbe1a822'	System	18 Aug 2020 05:00:25
User entered 'No (N)'	System	18 Aug 2020 05:00:25

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:18', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '7423ace8-c508-4f90-adba-516ccbe1a822'	System	18 Aug 2020 05:00:25
User entered 'None (1)'	System	18 Aug 2020 05:00:25

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:21', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '7423ace8-c508-4f90-adba-516ccbe1a822'	System	18 Aug 2020 05:00:25
User entered '18 Aug 2020 00:00'	System	18 Aug 2020 05:00:25

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 5'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 6'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:23', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '59441267-0360-45e7-99fd-504f29bb570e'	System	19 Aug 2020 18:18:39
User entered 'None (1)'	System	19 Aug 2020 18:18:39

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:27', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '59441267-0360-45e7-99fd-504f29bb570e'	System	19 Aug 2020 18:18:39
User entered 'No (N)'	System	19 Aug 2020 18:18:39

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:31', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '59441267-0360-45e7-99fd-504f29bb570e'	System	19 Aug 2020 18:18:39
User entered 'No (N)'	System	19 Aug 2020 18:18:39

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:33', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '59441267-0360-45e7-99fd-504f29bb570e'	System	19 Aug 2020 18:18:39
User entered 'None (1)'	System	19 Aug 2020 18:18:39



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:36', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '59441267-0360-45e7-99fd-504f29bb570e'	System	19 Aug 2020 18:18:39
User entered '19 Aug 2020 13:18'	System	19 Aug 2020 18:18:39

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 7'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:12', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96ee76de-d4cb-4d11-9833-2b91c3403563'	System	21 Aug 2020 01:28:28
User entered 'None (1)'	System	21 Aug 2020 01:28:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:14', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96ee76de-d4cb-4d11-9833-2b91c3403563'	System	21 Aug 2020 01:28:28
User entered 'No (N)'	System	21 Aug 2020 01:28:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:16', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96ee76de-d4cb-4d11-9833-2b91c3403563'	System	21 Aug 2020 01:28:28
User entered 'No (N)'	System	21 Aug 2020 01:28:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:20', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96ee76de-d4cb-4d11-9833-2b91c3403563'	System	21 Aug 2020 01:28:28
User entered 'None (1)'	System	21 Aug 2020 01:28:28



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:24', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96ee76de-d4cb-4d11-9833-2b91c3403563'	System	21 Aug 2020 01:28:28
User entered '20 Aug 2020 20:28'	System	21 Aug 2020 01:28:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:05', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered 'None (0)'	System	14 Aug 2020 16:45:36

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:07', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered 'None (0)'	System	14 Aug 2020 16:45:36

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:12', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered 'None (0)'	System	14 Aug 2020 16:45:36

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:14', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered 'None (0)'	System	14 Aug 2020 16:45:36



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:17', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered 'None (0)'	System	14 Aug 2020 16:45:36

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:19', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered 'None (0)'	System	14 Aug 2020 16:45:36

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:29', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered 'No (N)'	System	14 Aug 2020 16:45:36

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-14T11:45:31', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2807ddd0-6e66-4811-a215-c6aee565982a'	System	14 Aug 2020 16:45:36
User entered '14 Aug 2020 11:45'	System	14 Aug 2020 16:45:36

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:31'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:01'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:27', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered 'None (0)'	System	15 Aug 2020 12:16:06



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:35', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered 'Some interference with activity (2)'	System	15 Aug 2020 12:16:06

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:39', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered 'None (0)'	System	15 Aug 2020 12:16:06

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:42', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered 'None (0)'	System	15 Aug 2020 12:16:06

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:50', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	15 Aug 2020 12:16:06

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:15:52', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered 'None (0)'	System	15 Aug 2020 12:16:06

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:16:00', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered 'No (N)'	System	15 Aug 2020 12:16:06

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T07:16:02', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cb06da81-f26d-4537-9d4b-f47173e878c3'	System	15 Aug 2020 12:16:06
User entered '15 Aug 2020 07:16'	System	15 Aug 2020 12:16:06

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:56'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 2'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:04:40', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered 'No interference with activity (1)'	System	16 Aug 2020 01:05:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:04:44', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered 'No interference with activity (1)'	System	16 Aug 2020 01:05:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:04:47', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered 'None (0)'	System	16 Aug 2020 01:05:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:04:59', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered 'No interference with activity (1)'	System	16 Aug 2020 01:05:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:05:08', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	16 Aug 2020 01:05:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:05:10', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered 'None (0)'	System	16 Aug 2020 01:05:28



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:05:21', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered 'No (N)'	System	16 Aug 2020 01:05:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-15T20:05:24', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1f961219-dcf7-424e-9932-22cd964c7564'	System	16 Aug 2020 01:05:28
User entered '15 Aug 2020 20:05'	System	16 Aug 2020 01:05:28

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 3'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:30', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered 'None (0)'	System	17 Aug 2020 02:43:55

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:32', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered 'None (0)'	System	17 Aug 2020 02:43:55

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:34', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered 'None (0)'	System	17 Aug 2020 02:43:55



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:36', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered 'None (0)'	System	17 Aug 2020 02:43:55

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:38', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered 'None (0)'	System	17 Aug 2020 02:43:55

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:40', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered 'None (0)'	System	17 Aug 2020 02:43:55

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:45', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered 'No (N)'	System	17 Aug 2020 02:43:55

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-16T21:43:49', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6a632eda-1db6-46b7-a226-034e86ffd3f7'	System	17 Aug 2020 02:43:55
User entered '16 Aug 2020 21:43'	System	17 Aug 2020 02:43:55

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 4'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:24', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered 'None (0)'	System	18 Aug 2020 05:00:47

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:27', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered 'None (0)'	System	18 Aug 2020 05:00:47

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:29', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered 'None (0)'	System	18 Aug 2020 05:00:47

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:31', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered 'None (0)'	System	18 Aug 2020 05:00:47

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:33', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered 'None (0)'	System	18 Aug 2020 05:00:47

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:35', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered 'None (0)'	System	18 Aug 2020 05:00:47

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:40', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered 'No (N)'	System	18 Aug 2020 05:00:47

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-18T00:00:42', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '2a28084a-2618-499c-b1f8-a24a72ac453b'	System	18 Aug 2020 05:00:47
User entered '18 Aug 2020 00:00'	System	18 Aug 2020 05:00:47



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 5'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 6'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:39', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered 'None (0)'	System	19 Aug 2020 18:19:07

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:44', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered 'None (0)'	System	19 Aug 2020 18:19:07



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:47', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered 'None (0)'	System	19 Aug 2020 18:19:07

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:49', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered 'None (0)'	System	19 Aug 2020 18:19:07

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:53', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered 'None (0)'	System	19 Aug 2020 18:19:07

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:55', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered 'None (0)'	System	19 Aug 2020 18:19:07

US3272144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered 'No (N)'	System	19 Aug 2020 18:19:07

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-19T13:18:59', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'a2bc1014-719d-46ea-b59c-21a0428e037d'	System	19 Aug 2020 18:19:07
User entered '19 Aug 2020 13:18'	System	19 Aug 2020 18:19:07

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 7'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:27', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered 'None (0)'	System	21 Aug 2020 01:28:46

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:28', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered 'None (0)'	System	21 Aug 2020 01:28:46

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:31', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered 'None (0)'	System	21 Aug 2020 01:28:46

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:33', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered 'None (0)'	System	21 Aug 2020 01:28:46

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:34', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered 'None (0)'	System	21 Aug 2020 01:28:46

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:36', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered 'None (0)'	System	21 Aug 2020 01:28:46

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:38', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered 'No (N)'	System	21 Aug 2020 01:28:46



**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-08-20T20:28:41', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c172be13-affb-4de8-bb46-3355ceec8152'	System	21 Aug 2020 01:28:46
User entered '20 Aug 2020 20:28'	System	21 Aug 2020 01:28:46

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:05:41

**US3272144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:05:41

**US3272144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 20:05:41

**US3272144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:05:41

**US3272144**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 19:48:23



**US3272144**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 19:48:23

**US3272144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 19:48:46

**US3272144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 19:48:46

**US3272144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 19:48:46

**US3272144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 19:48:46

**US3272144**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 19:48:50

**US3272144**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 19:48:50

**US3272144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:52



**US3272144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:52

**US3272144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:52

**US3272144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:52

**US3272144**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:56

**US3272144**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Sep 2020 02:18:56

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:49:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 17:49:01

US3272144

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 17:49:01



**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Sep 2020 17:49:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '11:18'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:18'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 17:50:21



**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '89'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '89'	(b) (4), (b) (6)	14 Sep 2020 17:50:21



**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '12:39'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:39'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 17:50:21



**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	(b) (4), (b) (6)	14 Sep 2020 17:50:21

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	14 Sep 2020 17:50:21



**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:50:21

US3272144

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:50:29

US3272144

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 17:50:29

US3272144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 17:17:11

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 17:17:11

US3272144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 17:17:11

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 17:17:11

US3272144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 17:17:11



US3272144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered '12:05'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 17:17:11

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:05'	System	11 Sep 2020 17:17:11

US3272144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:48

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 17:17:11

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:48**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:50:46

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 17:50:46

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:37'	(b) (4), (b) (6)	14 Sep 2020 17:50:46



**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:37'	System	14 Sep 2020 17:50:46

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 10:51:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 17:51:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 17:51:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:51:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '11:30'	(b) (4), (b) (6)	14 Sep 2020 17:51:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:30'	System	14 Sep 2020 17:51:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 17:51:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 17:51:01



**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:51:01

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:51:01

US3272144

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:51:07

**US3272144**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 17:51:07

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:41:45', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'bbefaf7c-c1a3-42bb-898f-b21c65cebefd'	System	11 Sep 2020 17:42:06
User entered 'Yes (Y)'	System	11 Sep 2020 17:42:06

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:41:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'bbefaf7c-c1a3-42bb-898f-b21c65cebefd'	System	11 Sep 2020 17:42:06
User entered '97.9'	System	11 Sep 2020 17:42:06

US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:42:00', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'bbefaf7c-c1a3-42bb-898f-b21c65cebefd'	System	11 Sep 2020 17:42:06
User entered 'No (N)'	System	11 Sep 2020 17:42:06



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:42:02', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'bbefaf7c-c1a3-42bb-898f-b21c65cebefd'	System	11 Sep 2020 17:42:06
User entered '11 Sep 2020 12:42'	System	11 Sep 2020 17:42:06

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:25'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:55'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:23:35', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6b771e74-bc2c-4162-8210-15ed41e62fe7'	System	12 Sep 2020 02:26:26
User entered 'Yes (Y)'	System	12 Sep 2020 02:26:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:23:42', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6b771e74-bc2c-4162-8210-15ed41e62fe7'	System	12 Sep 2020 02:26:26
User entered '98.3'	System	12 Sep 2020 02:26:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:23:45', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6b771e74-bc2c-4162-8210-15ed41e62fe7'	System	12 Sep 2020 02:26:26
User entered 'No (N)'	System	12 Sep 2020 02:26:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:23:49', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6b771e74-bc2c-4162-8210-15ed41e62fe7'	System	12 Sep 2020 02:26:26
User entered '11 Sep 2020 21:23'	System	12 Sep 2020 02:26:26



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:50'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 2'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:05', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '071f41c2-2edd-4cc3-8b5d-10a3bd8e85a5'	System	13 Sep 2020 03:21:25
User entered 'Yes (Y)'	System	13 Sep 2020 03:21:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:11', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '071f41c2-2edd-4cc3-8b5d-10a3bd8e85a5'	System	13 Sep 2020 03:21:25
User entered '97.9'	System	13 Sep 2020 03:21:25

US3272144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:14', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '071f41c2-2edd-4cc3-8b5d-10a3bd8e85a5'	System	13 Sep 2020 03:21:25
User entered 'No (N)'	System	13 Sep 2020 03:21:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:21', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '071f41c2-2edd-4cc3-8b5d-10a3bd8e85a5'	System	13 Sep 2020 03:21:25
User entered '12 Sep 2020 22:21'	System	13 Sep 2020 03:21:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 3'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:09:40', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '8c946dae-8353-44cf-a021-fdc4bd7442d7'	System	14 Sep 2020 04:09:55
User entered 'Yes (Y)'	System	14 Sep 2020 04:09:55

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:09:48', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '8c946dae-8353-44cf-a021-fdc4bd7442d7'	System	14 Sep 2020 04:09:55
User entered '98.1'	System	14 Sep 2020 04:09:55

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:09:30', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '8c946dae-8353-44cf-a021-fdc4bd7442d7'	System	14 Sep 2020 04:09:55
User entered 'No (N)'	System	14 Sep 2020 04:09:55

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:09:52', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '8c946dae-8353-44cf-a021-fdc4bd7442d7'	System	14 Sep 2020 04:09:55
User entered '13 Sep 2020 23:09'	System	14 Sep 2020 04:09:55

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 4'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-14T23:59:48', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76fd775a-7763-472b-b9ae-fe23a16fe8d3'	System	15 Sep 2020 05:00:09
User entered 'Yes (Y)'	System	15 Sep 2020 05:00:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-14T23:59:56', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76fd775a-7763-472b-b9ae-fe23a16fe8d3'	System	15 Sep 2020 05:00:09
User entered '97.8'	System	15 Sep 2020 05:00:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-14T23:59:58', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76fd775a-7763-472b-b9ae-fe23a16fe8d3'	System	15 Sep 2020 05:00:09
User entered 'No (N)'	System	15 Sep 2020 05:00:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:01', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76fd775a-7763-472b-b9ae-fe23a16fe8d3'	System	15 Sep 2020 05:00:09
User entered '15 Sep 2020 00:00'	System	15 Sep 2020 05:00:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 5'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:42:59', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '77d5821d-d16e-4777-86a4-db39decec0b1'	System	16 Sep 2020 01:43:13
User entered 'Yes (Y)'	System	16 Sep 2020 01:43:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:04', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '77d5821d-d16e-4777-86a4-db39decec0b1'	System	16 Sep 2020 01:43:13
User entered '98.2'	System	16 Sep 2020 01:43:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:07', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '77d5821d-d16e-4777-86a4-db39decec0b1'	System	16 Sep 2020 01:43:13
User entered 'No (N)'	System	16 Sep 2020 01:43:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:10', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '77d5821d-d16e-4777-86a4-db39decec0b1'	System	16 Sep 2020 01:43:13
User entered '15 Sep 2020 20:43'	System	16 Sep 2020 01:43:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 6'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:54:43', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1a08697a-1532-4fad-aebf-0b60b7c6c7e8'	System	17 Sep 2020 12:55:04
User entered 'Yes (Y)'	System	17 Sep 2020 12:55:04



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:54:51', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1a08697a-1532-4fad-aebf-0b60b7c6c7e8'	System	17 Sep 2020 12:55:04
User entered '98.5'	System	17 Sep 2020 12:55:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:54:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1a08697a-1532-4fad-aebf-0b60b7c6c7e8'	System	17 Sep 2020 12:55:04
User entered 'No (N)'	System	17 Sep 2020 12:55:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:54:59', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '1a08697a-1532-4fad-aebf-0b60b7c6c7e8'	System	17 Sep 2020 12:55:04
User entered '17 Sep 2020 07:54'	System	17 Sep 2020 12:55:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 7'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:45', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6561adcb-ddaa-40de-a3ba-a7eabe3f466b'	System	11 Sep 2020 17:34:09
User entered 'None (1)'	System	11 Sep 2020 17:34:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:48', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6561adcb-ddaa-40de-a3ba-a7eabe3f466b'	System	11 Sep 2020 17:34:09
User entered 'No (N)'	System	11 Sep 2020 17:34:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:52', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6561adcb-ddaa-40de-a3ba-a7eabe3f466b'	System	11 Sep 2020 17:34:09
User entered 'No (N)'	System	11 Sep 2020 17:34:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:34:00', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6561adcb-ddaa-40de-a3ba-a7eabe3f466b'	System	11 Sep 2020 17:34:09
User entered 'None (1)'	System	11 Sep 2020 17:34:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:34:03', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '6561adcb-ddaa-40de-a3ba-a7eabe3f466b'	System	11 Sep 2020 17:34:09
User entered '11 Sep 2020 12:34'	System	11 Sep 2020 17:34:09

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:25'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:55'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:23:56', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ed9ea78d-bede-4871-bc69-e0be9390da77'	System	12 Sep 2020 02:28:23
User entered 'None (1)'	System	12 Sep 2020 02:28:23

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:23:58', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ed9ea78d-bede-4871-bc69-e0be9390da77'	System	12 Sep 2020 02:28:23
User entered 'No (N)'	System	12 Sep 2020 02:28:23

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:00', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ed9ea78d-bede-4871-bc69-e0be9390da77'	System	12 Sep 2020 02:28:23
User entered 'No (N)'	System	12 Sep 2020 02:28:23

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:02', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ed9ea78d-bede-4871-bc69-e0be9390da77'	System	12 Sep 2020 02:28:23
User entered 'None (1)'	System	12 Sep 2020 02:28:23

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:05', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'ed9ea78d-bede-4871-bc69-e0be9390da77'	System	12 Sep 2020 02:28:23
User entered '11 Sep 2020 21:24'	System	12 Sep 2020 02:28:23

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:50'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 2'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:25', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'fda743ff-822a-4c34-986b-397ce685a8db'	System	13 Sep 2020 03:21:46
User entered 'None (1)'	System	13 Sep 2020 03:21:46

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:29', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'fda743ff-822a-4c34-986b-397ce685a8db'	System	13 Sep 2020 03:21:46
User entered 'No (N)'	System	13 Sep 2020 03:21:46

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:37', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'fda743ff-822a-4c34-986b-397ce685a8db'	System	13 Sep 2020 03:21:46
User entered 'No (N)'	System	13 Sep 2020 03:21:46

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:39', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'fda743ff-822a-4c34-986b-397ce685a8db'	System	13 Sep 2020 03:21:46
User entered 'None (1)'	System	13 Sep 2020 03:21:46

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:43', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'fda743ff-822a-4c34-986b-397ce685a8db'	System	13 Sep 2020 03:21:46
User entered '12 Sep 2020 22:21'	System	13 Sep 2020 03:21:46

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 3'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:09:56', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c4bcf0ad-1e27-4343-a15b-06fb3f14e504'	System	14 Sep 2020 04:10:10
User entered 'None (1)'	System	14 Sep 2020 04:10:10

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:09:58', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c4bcf0ad-1e27-4343-a15b-06fb3f14e504'	System	14 Sep 2020 04:10:10
User entered 'No (N)'	System	14 Sep 2020 04:10:10

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:01', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c4bcf0ad-1e27-4343-a15b-06fb3f14e504'	System	14 Sep 2020 04:10:10
User entered 'No (N)'	System	14 Sep 2020 04:10:10

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:03', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c4bcf0ad-1e27-4343-a15b-06fb3f14e504'	System	14 Sep 2020 04:10:10
User entered 'None (1)'	System	14 Sep 2020 04:10:10

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:05', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'c4bcf0ad-1e27-4343-a15b-06fb3f14e504'	System	14 Sep 2020 04:10:10
User entered '13 Sep 2020 23:10'	System	14 Sep 2020 04:10:10

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 4'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:04', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '68ff3191-ef70-48bc-b766-95985cfdda7a'	System	15 Sep 2020 05:00:16
User entered 'None (1)'	System	15 Sep 2020 05:00:16

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:06', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '68ff3191-ef70-48bc-b766-95985cfdda7a'	System	15 Sep 2020 05:00:16
User entered 'No (N)'	System	15 Sep 2020 05:00:16

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:08', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '68ff3191-ef70-48bc-b766-95985cfdda7a'	System	15 Sep 2020 05:00:16
User entered 'No (N)'	System	15 Sep 2020 05:00:16

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:10', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '68ff3191-ef70-48bc-b766-95985cfdda7a'	System	15 Sep 2020 05:00:16
User entered 'None (1)'	System	15 Sep 2020 05:00:16

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:12', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '68ff3191-ef70-48bc-b766-95985cfdda7a'	System	15 Sep 2020 05:00:16
User entered '15 Sep 2020 00:00'	System	15 Sep 2020 05:00:16

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 5'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:14', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'e42e782d-0ca7-4077-89a2-1ee5a592bb1e'	System	16 Sep 2020 01:43:26
User entered 'None (1)'	System	16 Sep 2020 01:43:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:16', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'e42e782d-0ca7-4077-89a2-1ee5a592bb1e'	System	16 Sep 2020 01:43:26
User entered 'No (N)'	System	16 Sep 2020 01:43:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:18', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'e42e782d-0ca7-4077-89a2-1ee5a592bb1e'	System	16 Sep 2020 01:43:26
User entered 'No (N)'	System	16 Sep 2020 01:43:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:20', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'e42e782d-0ca7-4077-89a2-1ee5a592bb1e'	System	16 Sep 2020 01:43:26
User entered 'None (1)'	System	16 Sep 2020 01:43:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:22', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'e42e782d-0ca7-4077-89a2-1ee5a592bb1e'	System	16 Sep 2020 01:43:26
User entered '15 Sep 2020 20:43'	System	16 Sep 2020 01:43:26

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 6'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:03', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '26393bf8-c736-4614-ac1a-a5e031ac5c7c'	System	17 Sep 2020 12:55:19
User entered 'None (1)'	System	17 Sep 2020 12:55:19

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:07', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '26393bf8-c736-4614-ac1a-a5e031ac5c7c'	System	17 Sep 2020 12:55:19
User entered 'No (N)'	System	17 Sep 2020 12:55:19

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:09', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '26393bf8-c736-4614-ac1a-a5e031ac5c7c'	System	17 Sep 2020 12:55:19
User entered 'No (N)'	System	17 Sep 2020 12:55:19

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:11', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '26393bf8-c736-4614-ac1a-a5e031ac5c7c'	System	17 Sep 2020 12:55:19
User entered 'None (1)'	System	17 Sep 2020 12:55:19

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:13', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '26393bf8-c736-4614-ac1a-a5e031ac5c7c'	System	17 Sep 2020 12:55:19
User entered '17 Sep 2020 07:55'	System	17 Sep 2020 12:55:19

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 7'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:14', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered 'None (0)'	System	11 Sep 2020 17:33:35

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:17', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered 'None (0)'	System	11 Sep 2020 17:33:35

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:18', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered 'None (0)'	System	11 Sep 2020 17:33:35

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:20', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered 'None (0)'	System	11 Sep 2020 17:33:35



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:21', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered 'None (0)'	System	11 Sep 2020 17:33:35

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:23', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered 'None (0)'	System	11 Sep 2020 17:33:35

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:26', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered 'No (N)'	System	11 Sep 2020 17:33:35

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T12:33:28', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'cab532df-2998-404b-9647-61cdfda70f63'	System	11 Sep 2020 17:33:35
User entered '11 Sep 2020 12:33'	System	11 Sep 2020 17:33:35

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:25'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:55'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:08', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered 'None (0)'	System	12 Sep 2020 02:30:13



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:14', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered 'No interference with activity (1)'	System	12 Sep 2020 02:30:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:17', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered 'None (0)'	System	12 Sep 2020 02:30:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:18', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered 'None (0)'	System	12 Sep 2020 02:30:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:20', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered 'None (0)'	System	12 Sep 2020 02:30:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:22', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered 'None (0)'	System	12 Sep 2020 02:30:13

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:30', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered 'No (N)'	System	12 Sep 2020 02:30:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-11T21:24:32', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '55067942-5e33-4c36-9c98-0d9558ae1027'	System	12 Sep 2020 02:30:13
User entered '11 Sep 2020 21:24'	System	12 Sep 2020 02:30:13

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:50'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 2'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:48', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered 'None (0)'	System	13 Sep 2020 03:22:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:50', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered 'None (0)'	System	13 Sep 2020 03:22:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:51', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered 'None (0)'	System	13 Sep 2020 03:22:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:53', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered 'None (0)'	System	13 Sep 2020 03:22:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:55', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered 'None (0)'	System	13 Sep 2020 03:22:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:57', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered 'None (0)'	System	13 Sep 2020 03:22:04



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:21:59', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered 'No (N)'	System	13 Sep 2020 03:22:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-12T22:22:01', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '96d9cac3-1e02-4f7e-a72f-3a7da3c2c11d'	System	13 Sep 2020 03:22:04
User entered '12 Sep 2020 22:22'	System	13 Sep 2020 03:22:04

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 3'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:09', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered 'None (0)'	System	14 Sep 2020 04:10:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:10', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered 'None (0)'	System	14 Sep 2020 04:10:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:11', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered 'None (0)'	System	14 Sep 2020 04:10:25



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:13', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered 'None (0)'	System	14 Sep 2020 04:10:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:15', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered 'None (0)'	System	14 Sep 2020 04:10:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:17', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered 'None (0)'	System	14 Sep 2020 04:10:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:19', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered 'No (N)'	System	14 Sep 2020 04:10:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-13T23:10:21', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'dfd96340-1583-4347-b304-3e3590569b8c'	System	14 Sep 2020 04:10:25
User entered '13 Sep 2020 23:10'	System	14 Sep 2020 04:10:25

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 4'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:15', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered 'None (0)'	System	15 Sep 2020 05:00:40

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:18', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered 'None (0)'	System	15 Sep 2020 05:00:40

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:19', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered 'None (0)'	System	15 Sep 2020 05:00:40

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:23', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered 'None (0)'	System	15 Sep 2020 05:00:40

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:24', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered 'None (0)'	System	15 Sep 2020 05:00:40

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:25', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered 'None (0)'	System	15 Sep 2020 05:00:40

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:30', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered 'No (N)'	System	15 Sep 2020 05:00:40

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T00:00:35', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '76404950-2987-446f-a781-d53e3208f726'	System	15 Sep 2020 05:00:40
User entered '15 Sep 2020 00:00'	System	15 Sep 2020 05:00:40



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 5'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:26', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered 'None (0)'	System	16 Sep 2020 01:43:47

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:28', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered 'None (0)'	System	16 Sep 2020 01:43:47

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:31', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered 'None (0)'	System	16 Sep 2020 01:43:47

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:33', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered 'None (0)'	System	16 Sep 2020 01:43:47

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:34', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered 'None (0)'	System	16 Sep 2020 01:43:47



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:36', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered 'None (0)'	System	16 Sep 2020 01:43:47

US3272144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:38', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered 'No (N)'	System	16 Sep 2020 01:43:47

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-15T20:43:41', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'd481adf6-468f-4566-a2cf-4541a4ba28b5'	System	16 Sep 2020 01:43:47
User entered '15 Sep 2020 20:43'	System	16 Sep 2020 01:43:47

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 6'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:17', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered 'None (0)'	System	17 Sep 2020 12:55:36

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:18', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered 'None (0)'	System	17 Sep 2020 12:55:36



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:19', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered 'None (0)'	System	17 Sep 2020 12:55:36

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:21', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered 'None (0)'	System	17 Sep 2020 12:55:36

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:22', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered 'None (0)'	System	17 Sep 2020 12:55:36

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:23', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered 'None (0)'	System	17 Sep 2020 12:55:36

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:26', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered 'No (N)'	System	17 Sep 2020 12:55:36

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-09-17T07:55:27', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: 'b8b65d16-c67b-4fcc-b8ad-2e54b0ef4dfe'	System	17 Sep 2020 12:55:36
User entered '17 Sep 2020 07:55'	System	17 Sep 2020 12:55:36

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:17:11



**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:17:11
User entered 'Day 7'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:17:11

**US3272144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 00:01:19

**US3272144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 00:01:19

**US3272144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 00:01:19

**US3272144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 00:01:19

**US3272144**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 00:01:28



**US3272144**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 00:01:28

**US3272144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 13:11:08

**US3272144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 13:11:08

**US3272144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Sep 2020 13:11:08

**US3272144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 13:11:08

US3272144

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 13:11:11

**US3272144**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Sep 2020 13:11:11

**US3272144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:21:54



**US3272144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 15:21:54

**US3272144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 15:21:54

**US3272144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 15:21:54

**US3272144**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:21:58

**US3272144**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 15:21:58

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:16:42

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 19:16:42

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 19:16:42



**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Oct 2020 19:16:42

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

US3272144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '09:34'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '06 Oct 2020 09:34'	System	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 19:18:24



**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 19:18:24

US3272144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

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

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '136'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:18:24

US3272144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	06 Oct 2020 19:18:24

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:18:24



**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:18:50

US3272144

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 19:18:50

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:19:08

US3272144

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 19:19:08

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:38'	(b) (4), (b) (6)	06 Oct 2020 19:19:08

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '06 Oct 2020 09:38'	System	06 Oct 2020 19:19:08

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:19:14

**US3272144**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 19:19:14



**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 64'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[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 (09cccd8ab37b510e)', Time: '2020-10-17T13:15:32', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '8193040d-b7a5-4e48-baba-b03f1668451f'	System	17 Oct 2020 18:15:52
User entered 'No (N)'	System	17 Oct 2020 18:15:52

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Have you been exposed to someone with 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 (09cccd8ab37b510e)', Time: '2020-10-17T13:15:44', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '8193040d-b7a5-4e48-baba-b03f1668451f'	System	17 Oct 2020 18:15:52
User entered 'No (N)'	System	17 Oct 2020 18:15:52

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-10-17T13:15:48', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '8193040d-b7a5-4e48-baba-b03f1668451f' User entered '17 Oct 2020 13:15:48'	System	17 Oct 2020 18:15:52
	System	17 Oct 2020 18:15:52

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 71'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[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 (09cccd8ab37b510e)', Time: '2020-10-21T14:28:01', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5643c06f-829a-41ae-8142-1f5bd347cd6b'	System	21 Oct 2020 19:28:22
User entered 'No (N)'	System	21 Oct 2020 19:28:22



**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Have you been exposed to someone with 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 (09cccd8ab37b510e)', Time: '2020-10-21T14:28:11', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5643c06f-829a-41ae-8142-1f5bd347cd6b'	System	21 Oct 2020 19:28:22
User entered 'No (N)'	System	21 Oct 2020 19:28:22

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-10-21T14:28:15', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '5643c06f-829a-41ae-8142-1f5bd347cd6b'	System	21 Oct 2020 19:28:22
User entered '21 Oct 2020 14:28:15'	System	21 Oct 2020 19:28:22

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 78'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[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 (09cccd8ab37b510e)', Time: '2020-10-28T00:01:26', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '28cde3e3-5430-460a-b793-89fe754bb4da'	System	28 Oct 2020 05:01:37
User entered 'No (N)'	System	28 Oct 2020 05:01:37

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Have you been exposed to someone with 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 (09cccd8ab37b510e)', Time: '2020-10-28T00:01:29', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '28cde3e3-5430-460a-b793-89fe754bb4da'	System	28 Oct 2020 05:01:37
User entered 'No (N)'	System	28 Oct 2020 05:01:37

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (09cccd8ab37b510e)', Time: '2020-10-28T00:01:32', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '28cde3e3-5430-460a-b793-89fe754bb4da'	System	28 Oct 2020 05:01:37
User entered '28 Oct 2020 00:01:32'	System	28 Oct 2020 05:01:37



**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered 'Day 92'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[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 (de8207af221fc1b8)', Time: '2020-11-11T13:56:21', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '002ffd5b-3b74-43fd-94fe-caddbf9dcfd1'	System	11 Nov 2020 19:56:57
User entered 'No (N)'	System	11 Nov 2020 19:56:57

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Have you been exposed to someone with 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 (de8207af221fc1b8)', Time: '2020-11-11T13:56:31', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '002ffd5b-3b74-43fd-94fe-caddbf9dcfd1'	System	11 Nov 2020 19:56:57
User entered 'Yes (Y)'	System	11 Nov 2020 19:56:57

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

Please 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 (de8207af221fc1b8)', Time: '2020-11-11T13:56:39', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '002ffd5b-3b74-43fd-94fe-caddbf9dcfd1'	System	11 Nov 2020 19:56:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 19:56:57

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de8207af221fc1b8)', Time: '2020-11-11T13:56:43', User OID: 'PatientReportedOutcome (US3272144)', ODM File OID: '002ffd5b-3b74-43fd-94fe-caddbf9dcfd1'	System	11 Nov 2020 19:56:57
User entered '11 Nov 2020 13:56:43'	System	11 Nov 2020 19:56:57

**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 16:39:11



**US3272144**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 16:39:11
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 16:39:11

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:23:48



**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:23:48
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:23:48

**US3272144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 18:52:47



**US3272144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '4 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 18:52:47

**US3272144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Nov 2020 18:52:47

**US3272144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:52:47

**US3272144**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 18:52:51

**US3272144**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 18:52:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:10
Query 'Please reconcile and add severity page as required' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 01:08:54
User opened query 'Please reconcile and add severity page as required' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:53:16
User entered '4 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 22:04:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:48**

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:10
User entered '12:42' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 17:57:06
User entered '14:55'	(b) (4), (b) (6)	04 Nov 2020 22:04:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:48**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Nov 2020 12:42'	System	05 Nov 2020 17:57:06
User entered '4 Nov 2020 14:55'	System	04 Nov 2020 22:04:34



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:48**

[Type of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because visit did not occurred during a Protocol Scheduled Visit, thanks.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:52:47
	(b) (4), (b) (6)	24 Nov 2020 15:20:10
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	04 Nov 2020 22:04:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:48**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 22:04:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '2 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 17:57:40
User entered '4 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 17:57:40
User entered '97'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 17:57:40
User entered '98.4' F	(b) (4), (b) (6)	04 Nov 2020 22:09:34



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 22:09:34



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '3 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:48

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:58:33

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 17:59:56



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '97'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '98.4' F	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:59:56

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '05 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '97'	(b) (4), (b) (6)	06 Nov 2020 16:56:44



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '98.2' F	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 16:56:44

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '96'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '98.8' F	(b) (4), (b) (6)	06 Nov 2020 17:00:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 17:00:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '7 Nov 2020'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '94'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '101.1' F	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Nov 2020 20:52:15

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '8 Nov 2020'	(b) (4), (b) (6)	08 Nov 2020 18:21:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '95'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '101.6' F	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Nov 2020 18:21:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '9 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '95'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '100.6' F	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	09 Nov 2020 23:09:55

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Andrea Clement (b) (4) (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '10 Nov 2020'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '94'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '100.6' F	Andrea Clement (b) (4)	10 Nov 2020 16:07:51



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	10 Nov 2020 16:07:51
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '92'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '98.3' F	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Nov 2020 20:10:40

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '12 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 15:28:52



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '92'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '98.7' F	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '13 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '93'	(b) (4), (b) (6)	14 Nov 2020 15:28:52



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '101.6' F	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:28:52

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '14 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '92'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '100.2' F	(b) (4), (b) (6)	14 Nov 2020 20:35:21



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 20:35:21



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '15 Nov 2020'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '95'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '100.0' F	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:48

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:36:47

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '91'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '97.0' F	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:51:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:51:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Severe (Severe)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '93'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '36.6' C	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:51:48

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '95'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '98.7' F	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '19 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '99'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '97.8' F	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:51:48

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 23:07:43
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:07:43

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '20 Nov 2020'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '96'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '96.8' F	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 22:33:49

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '21 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '97'	(b) (4), (b) (6)	21 Nov 2020 16:32:08



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '98.0' F	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 16:32:08

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 21 (Day 21)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '22 Nov 2020'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered '0'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please confirm O2 and Temperature were not collected. If yes, ensure deviation reporting, thanks.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:53:43
	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	22 Nov 2020 18:11:28
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered missing code ND - Not Done.	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 26 Nov 2020 10:51:48**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:02
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:11:28



US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:48

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-NOV-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 04NOV2020 is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:10:20
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-NOV-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 04NOV2020 is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.' answered with 'used unscheduled kit for illness visit as study site ran out of illness kits' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 23:22:56
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-NOV-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 04NOV2020 is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:39:16
User entered '4 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 22:09:57

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 22:09:57

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:48

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
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)	23 Nov 2020 14:57:48
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 'yes' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 23:23:12
Query 'Please verify as positive results sent to site by central lab' canceled (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 20:48:42
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	12 Nov 2020 23:13:26
User entered 'Yes (Y)' reason for change: New Information	Andrea Clement (b) (4)	12 Nov 2020 23:13:26
User opened query 'Please verify as positive results sent to site by central lab' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:53:48
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 22:09:57

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User entered '4 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 22:09:57

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	04 Nov 2020 22:09:57

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:09:57

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 22:09:57

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:09:57



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:09:57

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:48**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 23:13:26
User entered '0'	System	04 Nov 2020 22:09:57

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	14 Nov 2020 20:36:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	14 Nov 2020 15:50:02
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User closed query 'Please verify as symptom log notes first instance of low O2 meeting criteria was on 11Nov2020' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 01:20:10
Query 'Please verify as symptom log notes first instance of low O2 meeting criteria was on 11Nov2020' answered with 'updatd' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:17:31
User entered '11 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:17:26
User opened query 'Please verify as symptom log notes first instance of low O2 meeting criteria was on 11Nov2020' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 01:10:09
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 20:59:21
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 20:36:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 15:50:02
User entered '11 Nov 2020'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please add End Date when available. Consider leaving this query open until date is available, thanks.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:01:01
User entered empty.	Andrea Clement (b) (4)	14 Nov 2020 20:59:21
	(b) (4)	12 Nov 2020 23:16:04

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered '92' reason for change: New Information	(b) (4), (b) (6)	14 Nov 2020 20:36:46
User entered empty; reason for change New Information	(b) (4), (b) (6)	14 Nov 2020 15:50:02
User entered '92'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:18:02
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User closed query 'Please verify as date should only be entered if answer to previous question = YES' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 01:20:30
Query 'Please verify as date should only be entered if answer to previous question = YES' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:18:09
User opened query 'Please verify as date should only be entered if answer to previous question = YES' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:52:19
User entered '13 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	14 Nov 2020 15:50:02
User entered '12 Nov 2020'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:16:04



**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:18:02
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

US3272144

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:51:48

[Date of Assessment](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please reconcile date of Radiographical Evidence. Concomitant procedures registered do not match with 13Nov20, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:55:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User closed query 'Please verify as date should only be entered if answer to previous question = YES' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 01:20:32
Query 'Please verify as date should only be entered if answer to previous question = YES' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:18:15
User opened query 'Please verify as date should only be entered if answer to previous question = YES' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:52:24
User entered '13 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	14 Nov 2020 15:50:02
User entered '12 Nov 2020'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:16:04

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:38
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:16:04
	(b) (4)	

**US3272144**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 10:51:48**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:20:43
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 23:07:10

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54



**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '8 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54



US3272144

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:51:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Please reconcile as positive swab from illness visit was received which means saliva samples to be collected and subject to remain in convalescent period through Illness Day 28 visit' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 01:19:46
Query 'Please reconcile as positive swab from illness visit was received which means saliva samples to be collected and subject to remain in convalescent period through Illness Day 28 visit' answered with 'subject in hospital' (Site from CRA).	Kayla Flege (b) (4)	20 Nov 2020 14:55:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 14:55:06
User opened query 'Please reconcile as positive swab from illness visit was received which means saliva samples to be collected and subject to remain in convalescent period through Illness Day 28 visit' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 20:48:17
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 23:06:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 23:06:30
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Andrea Clement (b) (4)	12 Nov 2020 23:06:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Nov 2020 20:12:54
	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:55:27
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 21:07:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 21:07:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:07:39
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:12:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:55:36
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 21:07:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 21:07:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:07:39
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:12:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:12:54



**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:55:36
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 21:07:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 21:07:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:07:39
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:12:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:12:54

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:04
User closed query 'Please reconcile and add saliva log' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 20:48:33
Query 'Please reconcile and add saliva log' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 21:06:33
User opened query 'Please reconcile and add saliva log' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:54:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:00:59

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:04
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:00:59

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Nov 2020 18:00:59

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	05 Nov 2020 18:00:59

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:02:09



**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '14:55'	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
User entered '4 Nov 2020 14:55'	System	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '187' cm	(b) (4), (b) (6)	05 Nov 2020 18:02:09
DataPoint set to visible.	System	05 Nov 2020 18:00:59

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '142.6' kg	(b) (4), (b) (6)	05 Nov 2020 18:02:09
DataPoint set to visible.	System	05 Nov 2020 18:00:59

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '98.4' F	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:02:09



**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '87'	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '20'	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '128'	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:11
User entered '79'	(b) (4), (b) (6)	05 Nov 2020 18:02:09

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 18:02:09



**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:02:19

**US3272144**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:17
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:02:19

US3272144

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:51:48

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:22:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:02:28

US3272144

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:51:48

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under illness Visit Day 1 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 10:00:06
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under illness Visit Day 1 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'used unscheduled kit for illness visit as study site ran out of illness kits' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:22:29
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under illness Visit Day 1 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 23:18:44
User entered '4 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 06:48:48
	(b) (4), (b) (6)	05 Nov 2020 18:02:28

US3272144

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:32
User closed query 'Please reconcile as central lab reported positive COVID result from illness visit' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 20:48:53
Query 'Please reconcile as central lab reported positive COVID result from illness visit' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 20:50:10
User entered 'Yes (Y)' reason for change: New Information	Andrea Clement (b) (4)	12 Nov 2020 22:47:25
User opened query 'Please reconcile as central lab reported positive COVID result from illness visit' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:54:55
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:20:51

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:14
User entered 'USA-US070-2020-mRNA-1273-P301000017'	System	13 Nov 2020 21:28:04
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 21:28:04

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
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)	12 Nov 2020 23:16:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:16:38
Data point term sent to Coder	System	12 Nov 2020 22:58:04
User entered 'CoVid 19 illness'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38



**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '2 Nov 2020'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:44:46
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'unknown' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:15:49
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:43:32
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	



**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'Grade 4 (Grade 4)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
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).		14 Nov 2020 20:48:11
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).		14 Nov 2020 20:48:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:57:38
User entered 'I'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '12 Nov 2020'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:21:11
DataPoint Un-verified.	Whitney West (b) (4)	23 Nov 2020 23:30:46
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 23:30:46
DataPoint Verified.	Whitney West (b) (4)	23 Nov 2020 23:30:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
	(b) (4), (b) (6)	
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 20:48:11
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	



**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 14:44:49
	(b) (4), (b) (6)	20 Nov 2020 16:21:25
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:16:23
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Whitney West (b) (4)	19 Nov 2020 23:09:44
	(b) (4)	
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:44:14
User entered 'None (NONE)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	



**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered '1'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:54:59
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
Query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' answered with 'udpated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:16:28
User entered '0' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:16:14
User opened query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:40:32
User entered '1'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 22:57:38

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:21:11
DataPoint Un-verified.	Whitney West (b) (4)	23 Nov 2020 23:30:46
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Whitney West (b) (4)	23 Nov 2020 23:30:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:44:51
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'still having symptoms' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:16:37
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:43:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 22:57:38
	(b) (4)	

US3272144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:21:11
DataPoint Un-verified.	(b) (4)	
	Whitney West (b) (4)	23 Nov 2020 23:30:46
User entered 'FIRST SYMPTOMS 2NOV2020, CONFIRMED COVID CONFIRMED 10NOV2020. SYMPTOMS WORSENING 11NOV2020, CONTACTED PCP AND WAS SENT RX COUGH SYRUP. APPOINTMENT 12NOV2020, ADMITTED TO GENERAL OBSERVATION. STABLE, NO O2 SUPPORT CURRENTLY. ACETAMINOPHEN AND ENOXAPARIN WHILE UNDER OBSERVATION. He returned home from the hospital 13NOV2020 with no new medications.	Whitney West (b) (4)	23 Nov 2020 23:30:46
	(b) (4)	
<p>Oxygenation remained around 92% and began having occurrences of bronchospasm. Returned to ED 16NOV2020 with hypoxia with saturations 80% and SOB. Was admitted to general floor 16NOV2020. Was given dexamethasone 6mg IV BID started 16NOV2020 until 18NOV2020, levofloxacin 500 mg PO started 17NOV2020, and remdesevir 200 mg IV x 1 and then 100 mg IV daily. Given 25 mg PO tramadol for a headache secondary to hypoxia on 17NOV2020. Was on 2L/NC during night, but was room air while awake. Given lactobacillus 1 billion units PO x 1 on 17NOV2020 for repeated episodes of diarrhea.</p> <p>Released from hospital care 19NOV2020. On room air, saturations at 98-99%, given prescription for zinc sulfate 220 mg PO daily, vitamin D3 2000 IU PO daily, levofloxacin, dexamethasone PO 6 mg daily, and Vitamin C 500 mg PO daily. Albuterol inhaler 180 mcg TID, started 18NOV2020. Instructions to follow up with PCP as needed.' reason for change: Data Entry Error</p>		
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:25
	(b) (4)	

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'First symptoms 2NOV2020, confirmed CoVid confirmed 10NOV2020. Symptoms worsening 11Nov2020, contacted PCP and was sent Rx cough syrup. Appointment 12Nov2020, admitted to general observation. Stable, no O2 support currently. Acetaminophen and Enoxaparin while under observation.'	Andrea Clement (b) (4)	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 22:57:38



**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 22:57:38

**US3272144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 22:57:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:51:48**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:21:14

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:23:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:23:26
Data point term sent to Coder	System	14 Aug 2020 18:22:21
User entered 'clonazepam'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'insomnia'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 18:22:18



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:22:18

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 20:28:02
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 18:22:18
User entered 'UN UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:22:18



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:22:18

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 18:22:18

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:24:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:24:29
Data point term sent to Coder	System	14 Aug 2020 18:23:23
User entered 'omeprazole'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	14 Aug 2020 18:23:09



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '10'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:23:09

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 20:28:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 18:23:09
User entered 'UN UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 18:23:09



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:23:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 18:23:09

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:25:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:25:16
Data point term sent to Coder	System	14 Aug 2020 18:24:28
User entered 'cetirizine'	(b) (4), (b) (6)	14 Aug 2020 18:24:06



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'seasonal allergies'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '10'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 18:24:06



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:06

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 20:28:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 18:24:06
User entered 'UN UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:24:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:24:06



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 18:24:06

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:52:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:52:13
Data point term sent to Coder	System	14 Aug 2020 18:25:30
User entered 'multi vitamin'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'nutritional health'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 18:24:43



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:43

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 20:28:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 18:24:43
User entered 'UN UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 18:24:43



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:24:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 18:24:43

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:25:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	04 Nov 2020 22:25:34
Data point term sent to Coder	System	04 Nov 2020 22:24:50
User entered 'influenza vaccine'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0.5'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mL (mL)'	(b) (4), (b) (6)	04 Nov 2020 22:24:38



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '18 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 22:24:38



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '18 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:24:38

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:24:38

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 21:26:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 21:26:35
Data point term sent to Coder	System	04 Nov 2020 22:25:51
User entered 'zyrtec'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'cat allergy'	(b) (4), (b) (6)	04 Nov 2020 22:25:40



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '10'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '4 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 22:25:40



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:25:40

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:25:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 22:25:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 22:25:44
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:25:40
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:25:40

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:25:40

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 21:58:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 21:58:52
Data point term sent to Coder	System	14 Nov 2020 21:43:16
Coding entries removed.	(b) (4), (b) (6)	14 Nov 2020 21:43:06
User entered 'tylenol' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:43:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:03:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:03:35
Data point term sent to Coder	System	12 Nov 2020 23:02:08
User entered 'Acetaminophen'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:01:33



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'CoVid 19 illness'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '325' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:43:28
User entered '650'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:01:33
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'as needed (PRN)'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:01:33
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:01:33
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '2 Nov 2020'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:01:33
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:01:33

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:01:33



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:01:33

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:22:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:22:39
Data point term sent to Coder	System	12 Nov 2020 23:04:10
User entered 'Pseudoephedrine'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Covid 19 illness'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '120'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:04:06
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'as needed (PRN)'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:04:06
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:04:06
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '7 Nov 2020'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:04:06



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:04:06

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:04:06

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:24:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:24:39
Data point term sent to Coder	System	12 Nov 2020 23:06:11
User entered 'Enoxaparin'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Deep Vein Thrombosis 2nd to Covid 19 illness'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '40'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:05:14
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Andrea Clement (b) (4)	12 Nov 2020 23:05:14
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '12 Nov 2020'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:44:50
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:05:14



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 21:44:50
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Andrea Clement (b) (4)	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 23:05:14

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 23:05:14

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: EUCALYPTUS GLOBULUS OIL;MENTHOL, PRODUCTSYNONYM: HALLS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:43:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:43:38
Data point term sent to Coder	System	14 Nov 2020 21:48:17
User entered 'halls cough drops'	(b) (4), (b) (6) (b) (4)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'covid 19'	(b) (4), (b) (6)	14 Nov 2020 21:47:30



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '1'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'lozenge'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'as needed (PRN)'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '13 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 21:47:30



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 21:47:30

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 21:47:30

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:22:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:22:58
Data point term sent to Coder	System	19 Nov 2020 14:08:51
User entered 'Remdesivir'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Covid 19'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '200'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once (ONCE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:07:54

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:07:54



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:07:54

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:24:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:24:03
Data point term sent to Coder	System	19 Nov 2020 14:09:53
User entered 'Remdesevir'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Covid 19'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '100'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:09:15



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:09:15

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:09:15

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:29:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:29:29
Data point term sent to Coder	System	19 Nov 2020 14:12:56
User entered 'Dexamethasone'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Covid 19'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '6'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'twice daily (BID)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:12:39

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:12:39

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:25:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:25:06
Data point term sent to Coder	System	19 Nov 2020 14:15:01
User entered 'Tramadol'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Headache secondary to hypoxia'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '25'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once (ONCE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:17:03
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 14:14:09

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	20 Nov 2020 14:17:03
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	19 Nov 2020 14:14:09
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 14:14:09
	(b) (4)	

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:14:09

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:14:09

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:25:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:25:13
Data point term sent to Coder	System	19 Nov 2020 14:17:04
User entered 'Levofloxacin'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Covid 19, prevention of secondary pneumonia'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '500'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:16:43

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:16:43



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:16:43

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:29:31
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 Nov 2020 14:29:31
Data point term sent to Coder	System	19 Nov 2020 14:18:05
User entered 'Dexamethasone'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Covid 19'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '6'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:17:41



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:17:41

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:17:41

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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)	19 Nov 2020 14:19:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:19:58
Data point term sent to Coder	System	19 Nov 2020 14:19:06
User entered 'Vitamin C'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Immune supplement'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '500'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:18:37

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:18:37

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:20:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:20:58
Data point term sent to Coder	System	19 Nov 2020 14:20:07
User entered 'Vitamin D3'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Immune Supplement'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '2000'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'IU (IU)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:19:56

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:19:56

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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)	19 Nov 2020 14:26:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:26:59
Data point term sent to Coder	System	19 Nov 2020 14:21:08
User entered 'Zinc Sulfate'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Immune Supplement'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '220'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:20:59

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:20:59



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:20:59

US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS ACIDOPHILUS, PRODUCTSYNONYM: LACTOBACILLUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:19:32
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
Data point term sent to Coder	System	19 Nov 2020 14:23:11
User entered 'Lactobacillus'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Diarrhea'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '1000000'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Other (OTHER)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'units'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'once (ONCE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20



US3272144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:51:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'Oral (ORAL)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:20:29
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 14:22:20



**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:22:20

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:51:48**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please go into SAE "COVID-19 Illness" page and mark checkbox for indicating Concomitant Procedures were performed, thanks.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	25 Nov 2020 00:50:45
	(b) (4), (b) (6) (b) (4)	20 Nov 2020 16:20:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:10:10
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 18:20:57

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:51:48**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:11:06

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered 'Chest x-ray'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:11:06

US3272144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:51:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	19 Nov 2020 23:12:57
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	19 Nov 2020 23:11:06
User entered 'Adverse Event (AE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:11:06

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:51:48**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 23:12:57
User entered 'Covid 19'	Whitney West (b) (4)	19 Nov 2020 23:11:06



**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:51:48**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:11:40

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered 'Chest x-ray'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:11:40

US3272144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:51:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	19 Nov 2020 23:12:34
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	19 Nov 2020 23:11:40
User entered 'Adverse Event (AE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:11:40

US3272144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:51:48

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 23:12:34
User entered 'Covid 19'	Whitney West (b) (4)	19 Nov 2020 23:11:40

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:51:48**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:12:05

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered 'Chest x-ray'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:12:05

US3272144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:51:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	19 Nov 2020 23:12:19
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	19 Nov 2020 23:12:05
User entered 'Adverse Event (AE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 23:12:05

**US3272144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:51:48**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:19:53
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 23:12:19
User entered 'Covid 19'	Whitney West (b) (4)	19 Nov 2020 23:12:05



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'USA-US070-2020-MRNA-1273-P301000017'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Adam'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Brosz'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '2444 W. Faidley Ave'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Grand Island'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'NE'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '68803'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:33:01
User entered 'US'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 16:30:15
User entered '4'	System	23 Nov 2020 14:47:34
User entered '3'	System	20 Nov 2020 21:35:27
User entered '2'	System	16 Nov 2020 14:33:08
User entered '1'	System	13 Nov 2020 21:28:30



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'USA-US070-2020-MRNA-1273-P301000017'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Adam'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Brosz'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '2444 W. Faidley Ave'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Grand Island'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'NE'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '68803'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:33:01
User entered 'US'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 16:30:15
User entered '4'	System	23 Nov 2020 14:47:34
User entered '3'	System	20 Nov 2020 21:35:27
User entered '2'	System	16 Nov 2020 14:33:08
User entered '1'	System	13 Nov 2020 21:28:30



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
User entered '13/Nov/2020 21:28'	System	13 Nov 2020 21:28:30

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:48

**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)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:33:01
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'USA-US070-2020-MRNA-1273-P301000017'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Adam'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Brosz'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '2444 W. Faidley Ave'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Grand Island'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'NE'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '68803'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:33:01
User entered 'US'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 16:30:15
User entered '4'	System	23 Nov 2020 14:47:34
User entered '3'	System	20 Nov 2020 21:35:27
User entered '2'	System	16 Nov 2020 14:33:08
User entered '1'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
User entered '16/Nov/2020 09:33'	System	16 Nov 2020 14:33:08

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:51:48

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:47:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 14:33:08

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'USA-US070-2020-MRNA-1273-P301000017'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Adam'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Brosz'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '2444 W. Faidley Ave'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Grand Island'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'NE'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '68803'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:33:01
User entered 'US'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 16:30:15
User entered '4'	System	23 Nov 2020 14:47:34
User entered '3'	System	20 Nov 2020 21:35:27
User entered '2'	System	16 Nov 2020 14:33:08
User entered '1'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:41:51
User entered '20/Nov/2020 16:35'	System	20 Nov 2020 21:35:27

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:51:48

**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)	23 Nov 2020 21:41:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:47:24
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 21:35:27

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'USA-US070-2020-MRNA-1273-P301000017'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Adam'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Brosz'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '2444 W. Faidley Ave'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Grand Island'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'NE'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '68803'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:33:01
User entered 'US'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 16:30:15
User entered '4'	System	23 Nov 2020 14:47:34
User entered '3'	System	20 Nov 2020 21:35:27
User entered '2'	System	16 Nov 2020 14:33:08
User entered '1'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:41:51
User entered '23/Nov/2020 14:47'	System	23 Nov 2020 14:47:34

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:51:48

**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)	23 Nov 2020 21:41:51
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 14:47:34



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'USA-US070-2020-MRNA-1273-P301000017'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Yes (Y)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'No (N)'	System	13 Nov 2020 21:28:04



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Adam'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Brosz'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '2444 W. Faidley Ave'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'Grand Island'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered 'NE'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 21:28:24
User entered '68803'	System	13 Nov 2020 21:28:04

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:21:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:33:01
User entered 'US'	System	13 Nov 2020 21:28:30

**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 16:30:15
User entered '4'	System	23 Nov 2020 14:47:34
User entered '3'	System	20 Nov 2020 21:35:27
User entered '2'	System	16 Nov 2020 14:33:08
User entered '1'	System	13 Nov 2020 21:28:30



**US3272144**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000017**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 10:51:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 11:30'	System	24 Nov 2020 16:30:15

US3272144

Folder: SAE USA-US070-2020-MRNA-1273-P301000017

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:51:48

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 16:30:15